# APPENDIX OF UNPUBLISHED AUTHORITIES

# APPENDIX A

2011 WL 1231577
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United States District Court,
S.D. Texas,
Houston Division.

UNITED STATES of America, ex rel. Elaine BENNETT, Plaintiffs,
v.
BOSTON SCIENTIFIC CORPORATION and Guidant Corporation, Defendants.

Civil Action No. H–07–2467.
|
March 31, 2011.

**Attorneys and Law Firms**

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**MEMORANDUM AND OPINION**

LEE H. ROSENTHAL, District Judge.

***1** This case is one of a number raising the question of when a manufacturer's promotion of a medical device for an "off-label" use may provide the basis for a *qui tam* action by a private plaintiff suing under the False Claims Act.[1] The relator, Elaine Bennett, alleges that Boston Scientific Corporation and Guidant Corporation improperly promoted the FlexView microwave surgical-ablation system for an off-label use and that these promotional activities caused physicians and hospitals to submit false claims for reimbursement from Medicare or Medicaid. The FDA has approved the defendants' microwave surgical-ablation system for the general uses of ablating soft tissue and striated, cardiac, and smooth muscle. The relators allege that the defendants have improperly promoted the device for the off-label use of surgical ablation to treat atrial fibrillation, both in conjunction with other cardiac surgery and as a stand-alone procedure.

The defendants have moved to dismiss under Rule 12(b)(6), applying the standards of Rule 8 and Rule 9(b) of the Federal Rules of Civil Procedure. The defendants argue that the allegations of off-label promotional activities are insufficient to plead that they caused physicians or hospitals to submit false reimbursement claims to Medicare or Medicaid. (Docket Entry No. 68). Bennett responded, (Docket Entry No. 75), and the defendants replied, (Docket Entry No. 77).

Based on the pleadings, the motion, the responses, and applicable law, this court grants the defendants' motion to dismiss, for the reasons explained in detail in this Memorandum and Opinion. Because there has been only one amendment, and because Rule 15 embodies a liberal amendment policy, the relators may amend no later than April 22, 2011, consistent with this Memorandum and Opinion.

## I. Background

### A. Procedural History

Elaine Bennett filed her complaint on November 9, 2006, under seal, to allow the United States to decide whether it wanted to intervene.[2] This is one of five *qui tam* actions filed by Elaine Bennett against medical-device manufacturers. (Docket Entry No. 4).[3] The United States has not intervened in this suit, but it has filed a "Statement of Interest in Response to the Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, (Docket Entry No. 73). The relator filed an amended complaint in July 2009, (Docket Entry No. 33), and an unredacted version of that complaint in December 2009, (Docket Entry No. 58).

### B. The Parties

Boston Scientific develops, manufactures, and markets medical devices, including surgical devices. On April 21, 2006, it acquired the codefendant, Guidant Corporation and its Cardiac Rhythm Management and Cardiac Surgery Divisions. Before the acquisition, Guidant had developed the FlexView microwave surgical-ablation system. (Docket Entry No. 58, ¶¶ 17–18).

Boston Scientific employed the relator, Elaine Bennett, for a short period—from June 12 to September 28, 2006—as a

 

sales representative in the Midwest region. Bennett worked in Central Illinois and throughout Missouri. (*Id.,* ¶ 16). In addition to her false claim allegations, Bennett alleges that the defendants retaliated against her for challenging the legality of their marketing practices. (*Id.,* ¶ 128).

**C. The False Claims Act**

***2** The False Claims Act prohibits the knowing submission of false or fraudulent claims for payment, or causing the submission of such claims, to the federal government, and prescribes fines and treble damages to penalize offenders. 31 U.S.C. § 3729(a). The FCA establishes liability for "[a]ny person who ... knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval ... [or] knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(1–2), *amended by* 31 U.S.C. § 3729(a)(1)(A–B).

When a *qui tam* suit is brought by a private relator and the government declines to intervene, the relator is entitled to between 25 and 30% of the recovery, § 3730(d)(2), as well as attorneys' fees. As has often been pointed out, the Act does not create a cause of action against all fraudulent conduct affecting the government. Rather, FCA liability attaches to a "false or fraudulent claim for payment" or to a "false record or statement [made] to get a false or fraudulent claim paid by the government." 31 U.S.C. § 3729(a)(1)-(2), *amended by* 31 U.S.C. § 37299(a) (1)(A–B). "Evidence of an actual false claim is the *'sine qua non* of a False Claims Act violation.' " *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.,* 290 F.3d 1301, 1311 (11th Cir.2002).

In this case, there are no allegations that the defendants themselves submitted false claims. Instead, the complaint alleges that the defendants knowingly caused the submission of fraudulent claims by physicians and hospitals. The fraudulent claims allegedly seek reimbursement for off-label uses of the defendants' devices. The complaint does not identify any specific false claim presented by others to Medicare/Medicaid. Nor does the complaint identify any entity or person who actually submitted such a claim. Instead, the complaint alleges that as a result of the defendants' marketing campaign and illegal kickbacks, the FlexView microwave surgical ablation system has been widely used for the off-label purpose of treating atrial fibrillation by physicians and hospitals and that this use "caused to be presented to the United States fraudulent claims ... in order to obtain reimbursement for surgical ablation services performed with Defendants' microwave surgical ablation products." (Docket Entry No. 58, ¶ 132).

**D. Off–Label Use of Medical Devices**

The FDA approves products for specific indications, which are stated in the label. When a medical device is approved for one purpose or indication and used outside this approved purpose, that use is deemed "off label." Off-label promotion may involve disseminating information about product uses the FDA did not approve. The FDA generally restricts a manufacturer from marketing for off-label purposes but does not restrict a hospital from purchasing, or a doctor from prescribing or using, a medical device for an off-label purpose. Off-label use of many devices and drugs is an accepted medical practice.[4]

***3** Courts recognize that off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device. *See Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 121 S.Ct. 1012, 1018, 148 L.Ed.2d 854 (2001) (" '[O]ff-label' usage of medical devices ... is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Svidler v. United States Dep't of Health and Human Servs.,* No. C–03–3593 MJJ, 2004 WL 2005781, at *5 (N.D.Cal. Sept.8, 2004) ("[T]he FDA can restrict a company from marketing off-label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary." (citing *Washington Legal Found. v. Friedman,* 13 F.Supp.2d 51 (D.D.C.1998)); *United States ex rel. Polansky v. Pfizer,* No. 04–cv–0704 (ERK), 2009 WL 1456582, at *6 (E.D.N.Y. May 22, 2009) ("[T]he FDA has acknowledged that 'accepted medical practice often includes drug use that is not reflected in approved drug labeling.' " (citing Food & Drug Admin., Use of Approved Drugs for Unlabeled Indications, 12 FDA Drug Bulletin 4, 5 (1982)); *United States ex rel. Stephens v. Tissue Sci. Labs., Inc.,* Civil Action No. 1:07–CV2357–ODE, LEXIS 2009 DIST. 101601, at *20 (N.D.Ga. Aug. 13, 2009) (noting that DRG payment may be made for hernia care even if noncovered care—the use of the device at issue—was present).

Medicare reimbursement for off-label uses of medical devices is not addressed within the Medicare Act itself. *See generally Yale—New Haven Hosp. v. Leavitt,* 470 F.3d 71, 73 (2d Cir.2006). Broad wording excludes from Medicare coverage "any expenses incurred for items or services ... which ... are

not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary of the Department of Health and Human Services "is responsible for specifying those services that are covered under the 'reasonable and necessary' standard" and "has wide discretion in selecting the means for doing so." *Yale—New Haven Hosp.,* 470 F.3d at 74 (citing 42 U.S.C. § 1395ff(a); *Heckler v. Ringer,* 466 U.S. 602, 617, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984)). Traditionally, the Secretary has acted through "formal regulations and (informal) instructional manuals and letters." *Id.* Before 1995, the Medicare Hospital Manual, the Medicare Carriers Manual, and the Intermediary Manual stated that payment could not be made for devices not approved by the FDA for commercial distribution because "they were not considered 'reasonable and necessary' under 42 U.S.C. § 1395y(a)(1)." *In re Cardiac Devices Qui Tam Litig.,* 221 F.R.D. 318, 323 (D.Conn.2004) (citing Medicare Hospital Manual § 260.1(B) (effective July 15, 1986); Medicare Carriers Manual § 230.1; Intermediary Manual § 3151.1)); *see also Yale—New Haven Hosp.,* 470 F.3d at 74 (discussing the history of the manual provisions). In 1995, the Secretary of the United States Department of Health and Human Services published regulations superseding the manual provisions and allowing Medicare coverage for Category B investigational devices under the "reasonable and necessary" standard. *Yale—New Haven Hosp.,* 470 F.3d at 71. As one court has summarized:

> ***4** On September 19, 1995, after completing a formal notice-andcomment rule-making process regarding coverage for investigational devices under the statutory 'reasonable and necessary' standard, the Secretary of HHS published final regulations addressing the coverage of medical devices categorized by the FDA as 'investigational.' The new regulations provided Medicare coverage for those 'nonexperimental/investigational' devices as to which the initial questions about the devices' safety and effectiveness had been resolved. *See* 42 C.F.R. § § 405.201(b), 405.203, 405.211(b). In contrast to the total exclusion from coverage of such devices under the Manual provision, the new regulations classified such devices as either experimental/investigational ('Category A') for which there continued to be no coverage, or non-experimental investigational ('Category B') which are eligible for Medicare coverage. *See* 42 C.F.R. §§ 405.201, 405.203(a), 405.205, 405.209, 405.211.

*In re Cardiac Devices Qui Tam Litig.,* 221 F.R.D. 318, 325 (D.Conn.2004).

The allegations in this case are that a Category B non-experimental/investigational medical device the FDA approved for a general use—ablating soft tissue and striated, cardiac, and smooth muscle in surgical procedures—is being marketed for a specific use that the FDA has not approved —to ablate cardiac tissue to treat atrial fibrillation. Atrial fibrillation is a fast and irregular beating of the heart's atria. The first-line treatments for atrial fibrillation are nonsurgical and include using drugs. (Docket Entry No. 58, ¶ 46–47). According to the relator, a recognized surgical treatment is an open-heart procedure known as the "maze." In a maze procedure, a cardiothoracic surgeon makes strategic incisions in both atria and uses a "cut and sew" technique to repair the heart. The maze procedure is effective but also dangerous and difficult. (*Id.,* ¶ 48). As a result, the medical community has continued efforts to find less invasive, more effective methods of treatment.

Two newer forms of treatment for atrial fibrillation are catheter ablation and surgical ablation. In catheter ablation, an electrophysiologist—a specialized cardiologist—threads a catheter through the patient's leg and into the heart. The catheter is equipped with a device that delivers microwaves to ablate heart tissue. The relator alleges that catheter ablation is often an outpatient procedure. (*Id.,* ¶¶ 50–52). The relator alleges that a large number of studies and scientific organizations have recently recognized catheter ablation as an effective procedure to treat atrial fibrillation. In 2006, catheter ablation was included within the "Guidelines" for treating atrial fibrillation as a "third-tier treatment option, following drug therapy and cardioversion." (*Id.,* ¶¶ 52–53).

The relator alleges that surgical ablation is a more recent method. Surgical ablation treats atrial fibrillation by using microwaves to ablate heart tissue and disrupt the normal pathways for electrical impulses. (*Id.,* ¶¶ 54–55). It is typically an inpatient procedure performed by cardiothoracic surgeons. It can be performed as an additional procedure during open-chest surgery for other cardiac conditions or as a stand-alone procedure. As part of other open-chest procedures, a surgeon uses the ablation device to make incisions on tissue similar to the incisions made in a "maze" procedure. In a stand-alone surgical ablation, a surgeon makes incisions on a patient's chest and directs an ablation device through those incisions to the heart. According to the relator, standalone surgical ablation, "unlike traditional open heart surgery—does not require opening the thoracic cavity to expose the heart and lungs and does not require putting the

patient on a heart-lung bypass machine to stop the heart." (*Id.,* ¶ 59). It is an inpatient but minimally invasive surgery.

***5** As the relator acknowledges, the FlexView system is classified for Medicare reimbursement purposes as a Class II device. (*Id.,* ¶ 73); *see also* 21 C.F.R. § 878.4400 (identifying "electrosurgical cutting and coagulation device and accessories ... intended to remove tissue and control bleeding by use of high-frequency electrical current" as a Class II device). Under Medicare regulations, a device "believed to be in ... Class II" is a Category B —"non-experimental/investigational"—device. 42 C.F.R. § 405.201(b). Class II devices "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. § 405.201(b). Medicare contractors may approve coverage for Category B devices. *Id.* at § 405.211(b). The relator acknowledges that there is no "[n]ational [c]overage [d]etermination" for reimbursement for microwave surgical ablation. "Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 58, ¶ 65). While there is no FDA approval for using the FlexView system to treat atrial fibrillation, there is no identified statutory, regulatory, or other prohibition on reimbursement to physicians or hospitals for using the FlexView system for this purpose. While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs, *see United States ex rel. Franklin v. Parke—Davis,* 147 F.Supp.2d 39, 44–45 (D.Mass.2001); *United States ex rel. Hess v. Sanofi—Synthelabo Inc.,* No. 4;05CV570MLM, 2006 WL 1064127, at *10 (E.D.Mo. Apr.21, 2006), the relator has not pointed to a similar categorical restriction on reimbursement for Category B medical devices.[5] For medical devices, eligibility for reimbursement depends on whether the procedure performed is "medically necessary" or "reasonable and necessary."

**E. The Medicare Billing System**

The Medicare billing scheme is the context for this FCA suit. Medicare prepays hospitals specific predetermined amounts based on codes for the diagnosis and procedure performed. (Docket Entry No. 58, ¶¶ 25, 28). The complex billing scheme includes a lengthy list of codes that reflect medical and administrative judgments.

The amounts hospitals receive for inpatient procedures depend on the Diagnosis Related Group ("DRG") code assigned to a patient. In addition to basic information about the patient and the diagnosis, the procedure performed on the patient is a factor in determining a patient's DRG. 42 C.F.R. § 412.60(c)(1) (stating that the DRG is based on "essential data extracted from the inpatient bill for that discharge" including "the patient's age, sex, principal diagnosis, ... secondary diagnoses, procedures performed, and discharge status"). Hospitals enter a procedure code when they submit Form HCFA–1450 (UB–92) to obtain reimbursement for items and services provided to a patient. *Cardiac Devices.,* 221 F.R.D. at 328–29; *United States ex rel. Smith v. Yale Univ.,* 415 F.Supp. 58, 91–92 (D.Conn.2006). These codes are based on the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD–9–CM") system. (Docket Entry No. 58, ¶ 27). In addition to Forms UB–92, hospitals annually submit a Hospital Cost Report, Form HCFA–2552, which summarizes the amounts of interim payments received and the amounts the hospital claims from Medicare. *Cardiac Devices.,* 221 F.R.D. at 328–29.

***6** The amounts Medicare pays physicians for services provided in conjunction with a procedure performed at a hospital are based on Current Procedural Terminology ("CPT") codes published by the American Medical Association. Physicians typically provide the CPT code and submit claims for payment on Form CMS–1500. (Docket Entry No. 58, ¶¶ 29–33, 37).

**F. The Medical Device at Issue**

The FlexView system includes a microwave generator a surgical-ablation probe "that delivers a continuous flow of microwave energy from the generator to the cardiac tissue" and "is designed to ablate tissue by the induction of cell death in targeted areas." (*Id.,* ¶ 60). The FlexView system can be used either in conjunction with other cardiac surgical procedures or for stand-alone surgical ablation. As noted, the FDA has approved the defendants' FlexView system for use in "the surgical ablation of soft tissue, and striated, cardiac, and smooth muscle." (*Id.,* ¶ 74). The FDA has denied general approval for the FlexView system as a treatment for atrial fibrillation.[6] (*Id.,* ¶ 79). The relator alleges, and the defendants accept as true for the purpose of this motion, that because the FDA has approved the FlexView system for general use and has not approved the FlexView system for treating atrial fibrillation, the defendants may not market the FlexView system for use in minimally invasive closed-chest surgical procedures for treating atrial fibrillation. (*Id.,* ¶ 81); *see* 21 C.F.R. § 812.7(a).

**G. The Alleged Improper Promotional Activities**

The relator alleges four categories of what she characterizes as actionable conduct by the defendants promoting off-label use of the FlexView system.

- The defendants instructed their sales representatives to train doctors to use the FlexView system to treat atrial fibrillation. Newly hired sales representatives were given a "ten-day 'New Hire Training' that focuses on using the [FlexView system] to treat atrial fibrillation." During the training, the defendants gave their new hires a document outlining "seven basic steps" for using the FlexView system to treat atrial fibrillation. Before the training's conclusion, the defendants required new hires to demonstrate an ability to "teach" physicians how to use the system to treat atrial fibrillation. The defendants required its sales representatives to accompany surgeons into the operating room and instruct them on using the system to treat atrial fibrillation. The defendants also used " 'Ablation Account Managers' who focused entirely on training surgeons to perform microwave surgical ablation to treat atrial fibrillation." (Docket Entry No. 58, ¶¶ 83–87).

- The defendants marketed the FlexView system to hospitals by emphasizing the high reimbursement-to-cost ratio available through using surgical ablation to treat atrial fibrillation in minimally invasive procedures. This is part of the "upcoding" allegations set out below. The defendants' promotional material emphasized the opportunity to obtain a favorable reimbursement-to-cost ratio. The promotional materials stated that there was a seven billion dollar market for reimbursements for the treatment of atrial fibrillation and that hospitals could receive approximately $5,000.00 per treatment by using the FlexView System to treat atrial fibrillation even when the costs to the hospital were far lower. The defendants also trained its sales representatives to "market the spread." The defendants instructed sales representatives to ask hospital executives, "Would you like to learn about a procedure with a large, untreated patient pool and favorable reimbursement"; provided sales representatives with powerpoint presentations emphasizing favorable reimbursements; and instructed sales representatives "to 'go after' hospitals who have a 'CEO and administration that understands the clinical and economic landscape.' " (Docket Entry No. 58, ¶¶ 88–93).

***7** • The defendants instructed their sales representatives to market the FlexView system by advising hospitals to "upcode" Medicare billings. The allegation is that Medicare could be billed for using the FlexView system using a DRG and procedure code for open-chest surgery.[7] The relator alleges that the defendants told sales representatives to tell hospitals that in closed-chest stand-alone atrial fibrillation procedures, they could bill Medicare using DRG 108 (excision or destruction of other lesion or tissue of heart, open approach), which is a code for "open-chest" procedures. The relator acknowledges that the DRG code associated with procedure code 37.33 is DRG 108. The relator alleges that the ICD–9 procedure code and the DRG codes are incorrect when used for closed-chest procedures. The relator alleges that because there is no procedure code that provides reimbursement for the closed-chest surgical ablation, "a more appropriate code ... would be procedure code 37.99 (other operations on heart and pericardium)," and DRG 110 or 111 (respectively, major cardiovascular procedures with and without complications and comorbidities). (*Id.,* ¶ 122). The relator alleges that the average reimbursement for a hospital under DRG 108 is $30,289 and the average cost to the hospital for patients who require procedures qualifying under that DRG is $31,074. In contrast, the average cost to the hospital of a closed-chest stand-alone surgical ablation is $10,650. The relator alleges that by training sales representatives to tell hospitals that they could bill Medicare for closed-chest stand-alone procedures using DRG and procedure codes for open-chest procedures, the defendants improperly promoted its FlexView system. (*Id.,* ¶¶ 116–24). This category of alleged actionable promotion by the defendants applies only to stand-alone procedures. The relator does not allege that the use of the FlexView in open-chest procedures that also treat other cardiac conditions is improperly billed using the codes for such procedures.

- The relator also alleges that the defendants provided remuneration to physicians and hospitals to encourage them to use the FlexView system, in violation of the antikickback statute, 42 U.S.C. § 1320a–7b(b). The relator alleges that the defendants provided in-kind services to physicians, particularly cardiothoracic surgeons, including referral services, marketing, and direct payments. (Docket Entry No. 58, ¶¶ 99–100). The relator alleges that the defendants sponsored meetings

to screen candidates for surgical ablation and referred them to cardiothoracic surgeons who used the FlexView system. (*Id.,* ¶ 103). The relator alleges that the defendants sponsored dinner programs and letter-writing services to present information about FlexView to primary care physicians who could make referrals. (*Id.,* ¶ 102). The relator alleges that the defendants also helped cardiothoracic surgeons advertise surgical ablation to treat atrial fibrillation, including producing marketing brochures that identified physicians who used the FlexView system to treat atrial fibrillation. (*Id.,* ¶ 104). Finally, the relator alleges that the defendants provided direct payments to physicians in the form of grants to physicians who promoted the FlexView system to other physicians. (*Id.,* ¶¶ 105). As to hospitals, the relator alleges that the defendants paid kickbacks in the forms of loans to purchase the FlexView equipment contingent on a minimum number, free products, such as generators to power FlexView components and disposable equipment used to perform surgical ablations, and discounts on other products contingent on a hospital's commitment to purchase a fixed number of ablation products. The relator alleges that the defendants offered these inducements on the condition that a hospital use the FlexView system for at least eighty percent of surgical ablation procedures. (*Id.* at ¶¶ 106–15). The relator alleges that the defendants' kickbacks caused false or fraudulent claims for payment to be submitted because certification of compliance with all applicable laws and regulations, including the antikickback statute, is a condition for payment under Medicare.

***8** The relator alleges that these promotional efforts "caused physicians and hospitals to perform an increased number of costly inpatient surgical ablation procedures in cases where less costly and less invasive treatments otherwise have been performed." (*Id.,* ¶ 131). The relator alleges that the defendants "knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for surgical ablation services performed with Defendants' microwave surgical ablation products." (*Id.* at ¶ 133).

The relator also alleges that the defendants violated the FCA's antiretaliation provisions. She alleges that she engaged in "protected conduct [that] put the Defendants on notice of the distinct possibility of a qui tam action" and that the defendants harassed her, threatened her, and ultimately discharged her. (*Id.,* ¶ 139–41). She also alleges that these acts violated Illinois law. (*Id.,* ¶¶ 142–46).

In their motion to dismiss under Rule 12(b)(6), the defendants argue that the relator has not alleged that they made any false claim or caused any false claim to be submitted to Medicare. The defendants emphasize both that the complaint does not link their marketing practices to the submission of specific false claims and that their promotional tactics are not "material" to the government's decisions to pay Medicare claims for surgical ablations. The defendants also argue that the relator did not allege sufficient facts to support a reasonable inference that hospitals or physicians falsely certified compliance with the antikickback statute. Finally, the defendants argue that the relator has not met Federal Rule of Civil Procedure 9(b)'s pleading requirements for fraud because she fails to identify the "who, what, when, where, and how of the alleged fraud." *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 903 (5th Cir.1997).

As to the FCA retaliation claims, the defendants argue that the relator failed to allege sufficient facts supporting her allegations. Specifically, the defendants argues that the relator has not alleged facts showing that she had engaged in a protected activity, that the defendants were aware she had engaged in a protected activity, or that her discharge was motivated by that protected activity. As to the Illinois retaliation claims, the defendants argue that Illinois law does not govern her allegations. Alternatively, the defendants argue that she has failed to plead sufficient facts supporting her state law claim.

The relator responds that the defendants' promotional efforts caused physicians and hospitals to perform more surgical ablations to treat atrial fibrillation than would otherwise have been performed and, as a result, more that were not medically necessary. *See* Docket Entry No. 75, at 9 ("[C]laims for reimbursement would not have been submitted to the Government *but for* Defendants' off-label promotion of medically unnecessary surgical ablation procedures using their Flex surgical ablation system."). As a result, physicians and hospitals submitted claims for reimbursement for procedures that were not medically necessary and that would not have been submitted but for the off-label promotion. *See* Docket Entry No. 75, at 9; 42 U.S.C. § 1320c–5(a)(3) ("medically necessary"); 42 U.S.C. § 1395y(a)(1)(A) ("reasonable and necessary"). The relator argues that using the FlexView system to treat atrial fibrillation is *never* medically necessary because the system is not FDA approved, is experimental, and is not a first-line treatment for this

purpose. The relator also argues that by marketing hospitals' ability to upcode stand-alone ablation procedures using the FlexView system, the defendants were the "but for" cause of hospitals and doctors submitting claims for payment with three false statements: that the code used accurately represented the procedure performed; that the procedure was the most economical, as required by 42 U.S.C. § 1320c–5(a)(1); and that the procedure was "medically necessary," as required by 42 U.S.C. § 1320c–5(a)(3). The relator also argues that the defendants' kickbacks caused physicians and hospitals falsely to certify—either implicitly in claims for payment, or expressly in annual compliance statements—compliance with the antikickback statute. The relator argues that the defendants' promotional efforts were material because their "natural tendency" was to cause the submission of false claims. Finally, the relator responds that she has provided sufficient factual allegations to meet the Rule 9(b) requirements for pleading a scheme to defraud.

***9** Each argument and response is analyzed below.

**II. The Legal Standards for a Motion to Dismiss**

The defendants moved under Rule 12(b)(6) to dismiss the allegations based on the alleged off-label promotion of the FlexView devices, the allegations of the antikickback statute in connection with the sale of these devices, and the retaliation allegations. Because FCA claims are fraud claims subject to the Rule 9(b) pleading requirements, *see Hopper v. Solvay Pharms.,* 588 F.3d 1318, 1325 (11th Cir.2009); *Thompson,* 125 F.3d at 903; *United States ex rel. Longhi v. Lithium Power Techs., Inc.,* 575 F.3d 458, 468 (5th Cir.2009), the defendants also moved to dismiss for failure to comply with these requirement. The parties also analyzed the application of 31 U.S.C. § 3729(a).

**A. Rule 12(b)(6)**

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b) (6). In *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), and *Ashcroft v. Iqbal,* —— U.S. ——, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), the Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). To withstand a Rule 12(b) (6) motion, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly,* 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly,* 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly,* 550 U.S. at 556). "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief-including factual allegations that when assumed to be true 'raise a right to relief above the speculative level." *Cuvillier v. Taylor,* 503 F.3d 397, 401 (5th Cir.2007) (footnote omitted) (quoting *Twombly,* 550 U.S. at 555); *see also S. Scrap Material Co. v. ABC Ins. Co. (In re S. Scrap Material Co.),* 541 F.3d 584, 587 (5th Cir.2008) (quoting *Twombly,* 550 U.S. at 555), *cert. denied,* 129 S.Ct. 1669 (2009). "Conversely, 'when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should ... be exposed at the point of minimum expenditure of time and money by the parties and the court.' " *Cuvillier,* 503 F.3d at 401 (quoting *Twombly,* 550 U.S. at 558).

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend under Rule 15(a) before dismissing with prejudice. *See Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.,* 313 F.3d 305, 329 (5th Cir.2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."); *see also United States ex rel. Adrian v. Regents of the Univ. of Cal.,* 363 F.3d 398, 403 (5th Cir.2004) ("Leave to amend should be freely given, and outright refusal to grant leave to amend without a justification ... is considered an abuse of discretion." (internal citation omitted)). However, a plaintiff should be denied leave to amend a complaint if the court determines that "the proposed change clearly is frivolous or advances a claim or defense that is legally insufficient on its face...." 6 Charles A. Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice And Procedure § 1487 (2d ed.1990); *see also Ayers v. Johnson,* 247 F. App'x 534, 535 (5th Cir.2007) (unpublished) (per curiam) (" '[A] district court acts within its discretion when dismissing a motion to amend that is frivolous or futile.' " (quoting *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.,* 195 F.3d 765, 771 (5th Cir.1999)).

**B. Rule 9(b)**

***10** "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *Thompson,* 125 F.3d at 903 (quoting *Williams v. WMX Techs., Inc.,* 112 F.3d 175, 179 (5th Cir.1997)). The pleader must "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Williams,* 112 F.3d at 177. " 'Rule 9(b)'s ultimate meaning is context specific, and thus there is no single construction of Rule 9(b) that applies in all contexts.' " *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 188 (5th Cir.2009) (quoting *Williams,* 112 F.3d at 178). In the context of the FCA, the parties dispute whether it is appropriate to relax the Rule 9(b) standard. The relator acknowledges that she has failed to identify a specific false claim but argues that this should not be required because the facts relating to the alleged fraud are "peculiarly within the perpetrator's knowledge" and the alleged fraud occurred over a multi-year period. (Docket Entry No. 75, at 25–27). The defendants respond that, to the contrary, the relevant information on billing and reimbursements are in the hands of third parties, including physicians, hospitals, and Medicare, and that there is no basis in the case law to relax the Rule 9(b) requirements in such circumstances. (Docket Entry No. 77, at 11–15).

### III. The False Claims Act

In *United States ex rel. Longhi v. Lithium Power Techs., Inc.,* the Fifth Circuit adopted a four-prong test for § 3729(a) claims. 575 F.3d 458 (5th Cir.2009). The Fifth Circuit requires: "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys."[8] *Id.* at 467 (adopting the test stated in *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370, 376 (4th Cir.2008)).

#### A. Which Version of the FCA Applies?

A threshold issue is whether the amended or earlier version of 31 U.S.C. § 3729 applies. The Fraud Enforcement Recovery Act of 2009 (FERA) amended sections of the False Claims Act, including two subsections implicated in this action, 31 U.S.C. § 3729(a)(1) and (2).[9] Pub.L. No. 111–21, § 386, 123 Stat. 1617 (2009). FERA became law on May 20, 2009. It contained a retroactivity provision stating as follows:

> The amendments made by this section shall take effect on the date of enactment of this Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 *et seq.*) that are pending on or after that date.

***11** 123 Stat. 1617 § 4(f). For the § 3729(a)(1) claim, this court must apply the pre-FERA version of § 3729(a)(1) because the relator filed this suit in November 2006, before the "date of [FERA's] enactment." Section 4(f)'s exception—"subparagraph (B) of section 3729(a)(1)"—applies to the § 3729(a)(2) claim. Section 4(f) states that the amended version of subsection (a)(2), now found at 31 U.S.C. § 3729(a)(1)(B), applies to all "claims" under the FCA pending on or after June 7, 2008. The pre- and post-FERA versions of the FCA define "claim" similarly. The pre-FERA FCA defines claim as

> [A]ny request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, guarantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c), *amended by* 31 U.S.C. § 3729(b)(2). The post-FERA amendments define "claim" as "any request or demand, whether under a contract or otherwise, for money or property ... [that] is presented to an officer, employee, or agent of the United States% y(4)27" 31 U.S.C. § 3729(b)(2). Neither definition refers to *cases* or causes of action under the FCA. Instead, both definitions refer to claims "for money or property" from the government. Because "claim" is a defined term in the FCA, the reference to "claims" in FERA § 4(f)(1) must be read in accordance with that definition. *See United States ex rel. Gonzales v. Fresenius Med. Care N. Am.,* No. EP–07–CV–247–PRM, 2010 WL 1645971, at *9 (W.D.Tex. Mar.31, 2010) (reaching the same conclusion). Under this approach, the post-FERA version of § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), applies if the false claims alleged by the relator were pending on or after June 7, 2008.

Most of the district courts that have ruled on this issue have reached the same conclusion. *See, e.g., United States ex rel. Compton v. Circle B Enters., Inc.,* No. 7:07–CV–32, 2010 WL 942293, at *2 n. 5 (M.D.Ga. Mar. 11, 2010) ("The revised version of section (a)(1)(B) does not apply to this case because none of Defendants' claims (the ... reimbursement claims) at issue here were pending on or after June 7, 2008."); *United States ex rel. Putnam v. E. Idaho Reg'l Med. Ctr.,* No. CIV. 4:07–192, 2010 WL 910751, at *4 (D.Idaho Mar.10, 2010) ("[B]ecause the claims for Medicaid reimbursement at issue in this case were neither pending on nor filed after June 7, 2008, the pre-FERA version of § 3729(a)(2) governs ...."); *Mason v. Medline Indus., Inc.,* No. 07–C–5615, 2010 WL 653542, at *3 (N.D.Ill. Feb.18, 2010) ("The court interprets § 4(f)(1) to apply to 'claims' as defined in the FCA. Accordingly, FERA's amendment does not apply retroactively to this case."); *United States ex rel. Sanders v. Allison Engine Co., Inc.,* 667 F.Supp.2d 747, 752 (S.D.Ohio 2009) ("[T]he clear indication from Congress is that the revised language at issue here is applicable to 'claims' pending on June 7, 2008, and not to 'cases' pending on June 7, 2008. Since the Defendants in this case had no 'claims' pending on June 7, 2008, the retroactivity clause does not apply to them ...."); *United States v. Sci. Applications Int'l Corp.,* 653 F.Supp.2d 87, 107 (D.D.C.2009) ("[S]ection 4(f)(1) will be interpreted to apply to 'claims' as defined in § 3729, that is, requests or demands for money or property. Thus, FERA has no impact on the present action.").

***12** The relator's amended complaint does not appear to involve claims pending on or after June 7, 2008. The amended complaint refers to 31 U.S.C. § 3729(a)(2), not 31 U.S.C. § 3729(a)(1)(B). The relator's allegations of unlawful promotional tactics date back to 2006 when she was employed by Boston Scientific. (Docket Entry No. 58, ¶ 16). The relator's allegations of false or fraudulent claim submission could, however, involve claims submitted after June 7, 2008. The defendants have pointed out that the FCA has been amended, (Docket Entry No. 68, at 4 n. 5). The relator has not argued whether the amended FCA or the prior version applies to their claims. The defendants argue that the result is the same under either version and the relator has not addressed this issue. (*Id.*).[10] In an abundance of caution, the analysis is conducted under both versions of the FCA because the amended complaint may cover claims pending on or after June 7, 2008.[11]

**B. The Elements of An FCA Claim**

**1. A False or Fraudulent Claim**

The Supreme Court has cautioned that the FCA does not punish every type of fraud committed on the government. *See United States v. McNinch,* 356 U.S. 595, 599, 78 S.Ct. 950, 2 L.Ed.2d 1001 (1958). "The [FCA] attaches liability, not to the underlying fraudulent activity, but to the 'claim for payment.' " *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1266–67 (9th Cir.1996) (finding on summary judgment that violation of Individuals with Disabilities Education Act regulations is not also an FCA violation unless compliance certification is a prerequisite to receive federal funds); *see also United States ex rel. Siewick v. Jamieson Sci. And Eng., Inc.,* 214 F.3d 1372, 1376–77 (D.C.Cir.2000) (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.,* 336 F.3d 375, 382–83 (5th Cir.2003) (upholding district court's dismissal because the plaintiff only alleged violations of HMO enrollment antidiscrimination laws but did not allege that the United States "conditioned payment ... on any implied certification of compliance with the anti-discriminatory provisions"); *United States ex rel. Roop v. Hypoguard USA, Inc.,* 559 F.3d 818, 824 (8th Cir.2009) (upholding district court's dismissal because the plaintiff alleged violations of the FDA medical-device-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

In the specific context of reimbursement claims for using a drug or device in a way that violates the FDA, the courts have held that the "mere fact" of "violating FDA regulations does not translate into liability for causing a false claim to be filed." *United States ex rel. Polansky v. Pfizer,* No. 04–cv–0704, 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009); *see also United States ex rel. Rost v. Pfizer, Inc.,* 507 F.3d 729, 732 (1 st Cir.2007), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662, 128 S.Ct. 2123, 170 L.Ed.2d 1030 (2008) (noting that the alleged marketing practices, "while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement"); *Thompson,* 125 F.3d at 902 ("[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.").

***13** The courts have held that a claim may be false or fraudulent under the FCA because it includes a certification of compliance with a federal statute, regulation, or contract that is a prerequisite to obtaining the government benefit. *United States ex rel. Graves v. ITT Educ. Servs., Inc.,* 284 F.Supp.2d 487, 497 (S.D.Tex.2003), *aff'd,* 111 F. App'x 296 (5th Cir. Oct.20, 2004). Such "legally false" certification differs from "factually false" certification, which involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided. *See Mikes v. Straus,* 274 F.3d 687 (2d Cir.2001). The Fifth Circuit has held that a claim is "legally false" only when a party affirmatively and explicitly certifies compliance with a statute or regulation and the certification is a condition to receiving the government benefit. *See Thompson,* 125 F.3d at 902. In addition to express certifications of compliance, other circuits have found that FCA liability may exist under an "implied theory" of certification. *See Willard,* 336 F.3d at 82 (discussing cases). "The theory of implied certification rests on the notion that 'where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent.' " *United States ex rel. Foster v. Bristol–Myers Squibb Co.,* 587 F.Supp.2d 805, 823 (E.D.Tex.2008) (citing *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.,* 251 F.Supp.2d 28, 33 (D.D.C.2003)). For example, the Sixth Circuit has found that FCA liability "can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned." *Willard,* 336 F.3d at 82 (quoting *United States ex rel. Augustine v. Century Health Servs., Inc.,* 289 F.3d 409, 415 (6th Cir.2002)). The Fifth Circuit has never adopted implied certification as a theory of FCA liability. *United States ex rel. Marcy v. Rowan Cos., Inc.,* 520 F.3d 384, 389 (5th Cir.2008) (citing *Willard,* 336 F.3d at 381–82); *United States v. Southland Mgmt. Corp.,* 326 F.3d 669, 679 (5th Cir.2003) (en banc) (Jones, J. concurring); *United States ex rel. Steury v. Cardinal Heath, Inc.,* 625 F.3d 262, 268 (5th Cir.2010). Instead, the Fifth Circuit has held that "[t]he violation of the statute or regulation does not create a cause of action under the False Claims Act; liability arises only if the defendant has made a false certification of compliance with the statute or regulation, when payment is conditioned on that certification." *Graves,* 284 F.Supp.2d at 497.

**2. Materiality**

Liability under both the pre- and post-FERA versions of the FCA requires that an actionable false statement be "material." *Longhi,* 575 F.3d at 467 (citing *Thompson,* 125 F.3d at 899); *see also Allison Engine Co., Inc. v. United States ex rel. Sanders,* 553 U.S. 662, 128 S.Ct. 2123, 2126, 170 L.Ed.2d 1030 (2008) (explaining that a § 3729(a) (2) "plaintiff must prove that the defendant intended that the false statement be material to the Government's decision to pay or approve the false claim"). The Fifth Circuit applies the "natural tendency" test to determine materiality. *Longhi,* 575 F.3d at 470. This test asks whether "the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is a result of indirect or intangible actions on the part of the Defendants." *Id.* "All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions." *Id.*

**3. Knowingly**

***14** An FCA claim must allege that the false statements were "knowingly" made or caused to be made. The FCA defines "knowing or knowingly" to mean "that a person, with respect to information," (i) "has actual knowledge of the information"; (ii) "acts in deliberate ignorance of the truth or falsity of the information"; or (iii) "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1–3). Because an FCA claim alleges a fraudulent or false statement knowingly made or caused to be made, *Longhi,* 575 F.3d at 468, "[c]laims brought under the FCA must comply with Rule 9(b)." *Thompson,* 125 F.3d at 903 (5th Cir.1997); *see also Hopper v. Solvay Pharms.,* 588 F.3d 1318, 1325 (11th Cir.2009). However, "[i]n contrast to common law fraud, the FCA "lacks the element of reliance and damages." *Grubbs,* 565 F.3d at 189. "It is adequate to allege that a false claim was knowingly presented regardless of its exact amount; the contents of the bill are less significant because a complaint need not allege that the Government relied on or was damaged by the false claim." *Id.* "To plead with particularity the circumstances constituting fraud for a FCA section [3729(a)(1)(A) ] claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. To plead with the requisite particularity a § 3729(a)(1)(B) claim, the complaint need not "allege details of fraudulent bills actually presented to the government." *Id.* at 192. The relator must, however,

allege facts linking a scheme to submit false claims to the submission of false claims. *Solvay Pharms.,* 588 F.3d at 1325.

**4. The Application of the Pleading Standards to FCA Claims**

Although the parties' discussion of Rule 12(b)(6) cites *Twombly* and *Iqbal* as the most recent statements by the Supreme Court under the rule, the arguments do not turn on a claim that the analysis and result in this case are different under those decisions than they would have been earlier. The parties' briefs do not argue whether the facts alleged are sufficient to make the claim of an FCA violation "plausible." Rather, the defendants argue that taking the facts alleged as true, as a matter of law, the FCA does not provide a basis for relief for the promotional activities and remuneration alleged.

The relator does argue for a relaxed application of Rule 9(b). (Docket Entry No. 75, at 24). The cases are clear that Rule 9(b) applies in FCA cases. *Longhi,* 575 F.3d at 468, *Thompson,* 125 F.3d at 903; *Hopper,* 588 F.3d at 1325. The cases also recognize two exceptions that the relator urges. "It is possible that the pleading requirements of Rule 9(b) may be relaxed in certain circumstances—when, for instance, the facts relating to the fraud are 'peculiarly within the perpetrator's knowledge.' " *United States ex rel. Doe v. Dow Chem. Co.,* 343 F.3d 325, 330 (5th Cir.2003) (quoting *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.,* 193 F.3d 304, 308 (5th Cir.1999). "Fraud may be pleaded on information and belief under such circumstances." *United States ex rel. Willard v. Humana Health Plan of Texas Inc.,* 336 F.3d 375, 385 (5th Cir.2003). But the Fifth Circuit has held that a plaintiff should not be relieved from complying with the Rule 9(b) requirements "where the documents containing the requisite information are in the possession of, and presumably available from, other sources." *United States ex rel. Rafizadeh v. Cont'l Common, Inc.,* 553 F.3d 869, 873 n. 6 (5th Cir.2008) (citing *Doe,* 343 F.3d at 330); *see also Polansky,* 2009 WL 1456582, at *8 ("The rationale for reducing the pleading burden when information is in the defendant's possession appears to spring from the fact that an adverse party would not willingly divulge incriminating information. Where the information needed to fill out the complaint is in the hands of third parties, rather than defendants, this rationale for reducing the pleading burden does not apply.").

***15** The Eleventh Circuit has held that the pleading standard should not be relaxed for *qui tam* plaintiffs who may have access to information only through discovery in suits where the government refuses to intervene, even though the government would have access to those documents without discovery. *Atkins,* 70 F.3d at 1360 & n. 17. The court reasoned:

> The *qui tam* relator bring the action *on behalf of* the federal government. The relator stands in the government's shoes—in neither a better nor worse position than the government stands when it brings suit. Accordingly, we cannot furnish a *qui tam* relator with an easier burden than the government would bear if it intervened and assumed the prosecution of the case. Permitting a *qui tam* relator to go forward with his complaint, when we would not allow the government to proceed, might encourage the government to evade its burden by merely recruiting a willing relator to file a *qui tam* action.

*United States ex. Rel. Atkins,* 470 F.3d 1350, 1360 (11th Cir.2006).

The relator argues that in *United States ex rel. Grubbs v. Kanneganti,* the Fifth Circuit relaxed the pleading standard for pleading fraud under the FCA. In *Grubbs,* the Fifth Circuit reversed the district court's dismissal of a *qui tam* suit alleging that psychiatrists billed Medicare and Medicaid for services not performed. 565 F.3d 180, 195 (5th Cir.2009). The *Grubbs* panel held that a *qui tam* plaintiff does not need to allege "the time, place, and contents of the false representation" in every case. 565 F.3 d at 191. The panel reasoned that requiring this level of detail "is one small step shy of requiring production of actual documentation with the complaint" and held that "to plead fraud with particularity ... a relator's complaint, if it cannot allege details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. *Grubbs* analyzed the Eleventh Circuit's decision in *Clausen,* which required allegations of the "specific contents of actually submitted claims, such as billing numbers, dates, and amounts." *Id.* at 186. Rejecting this requirement, the *Grubbs* court stated as follows:

> [T]he "time, place, contents, and identity" standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act. We reach for a workable construction of Rule 9(b) with complaints under the False Claims Act; that is, one that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud. We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's

complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

***16** *Id.* at 190.

The relator argues that this court should relax the pleading standard because she does not have access to certain information. In the Fifth Circuit, the pleading standard is not relaxed when such information is available from third party entities and individuals. *Rafizadeh,* 553 F.3d at 873 n. 6. The defendants note that it does not have billing or reimbursement information; doctors, hospitals, and government agencies do. There is no basis to relax the Rule 9(b) pleading standard on this ground under the applicable precedents. *See Polansky,* 2009 WL 1456582, at *8 (refusing to relax the pleading standard in off-label *qui tam* against drug manufacturer because the needed information available was not in the hands of the defendants but in the hands of third parties).

The First Circuit has held that "in situations ... where the defendant induced third parties to file false claims ... a more flexible standard applies." *United States ex rel. Westmoreland v. Amgen, Inc.,* 738 F.Supp.2d 267, 275 (D.Mass.2010) (quoting *United States ex rel. Duxbury v. Ortho Biotech. Prods.,* 579 F.3d 13, 29 (1st Cir.2009)). For these claims, "[a] relator can satisfy Rule 9(b) by providing 'factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details of each false claim." *Id.* If *Grubbs* states a similar approach, it also emphasizes that district courts must look to whether the plaintiff alleges either at least some false claims with particularity or, if she cannot, alleges both particular details of the scheme to submit false claims and reliable indicia that lead to a strong inference that false claims were actually submitted. *Compare United States ex rel. Carpenter,* 723 F.Supp.2d 395, 408 (D.Mass.2010) (dismissing allegations of an off-label pharmaceutical kickback scheme because the relator could not "offer any particulars as to names, dates, amounts, or the incentives doctors are alleged to have been offered") *with id.* at 407–08 (denying motion to dismiss off-label prescription reimbursement allegations where the relator alleged a detailed description of eight false claims which included: the patient's identity, the patient's drug history to show that the prescription was off-label, the date of the claim, the Medicare of Medicaid program to which the bill was submitted, the location of the submitting pharmacy, the dosage, the dollar amount billed, the initials of the pharmacist who filled the prescription, and the name of the doctor who wrote it). *See also Duxbury,* 579 F.3d at 29–30 (finding that relator alleging that defendant caused off-label prescriptions alleged fraud with particularity by identifying eight healthcare providers that submitted false claims, the dates of the false claims, and the amounts of the false claims, but noting that the allegations still presented a "close call"); *United States ex rel. Piacentile v. Sanofie Synthelabo, Inc.,* Civ. A. No. 05–2927, 2010 WL 5466043, at *7–9 (D.N.J. Dec. 30, 2010) (noting that courts have not required the relator to "allege the details of particular claims" when the allegations are that the defendant caused false claims to be submitted, but finding the relator's allegations insufficient under this standard because he could not identify one physician who wrote an off-label description because of the defendant's marketing).

***17** The relator also urges this court to relax the Rule 9(b) pleading standard because the alleged fraud occurred over an extended period of time and consists of numerous acts." *Bristol—Myers Squibb Co. .,* 587 F.Supp.2d at 821 (listing cases). Courts have allowed the plaintiff to "plead the fraudulent scheme with particularity and provide representative examples of specific fraudulent acts conducted pursuant to that scheme." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.,* 501 F.3d 493, 509–10 (6th Cir.2007); *see also Barrett,* 251 F.Supp.2d at 35 ("While a complaint that covers a multi-year period may not be required by Rule 9(b) to contain a detailed allegation of all facts supporting each and every instance of submission of a false claim, some information on the false claims must be included." (citing *United States ex rel. Lee v. SmithKline Beecham, Inc.,* 245 F.3d 1048, 1051 (9th Cir.2001)). The relator in the present case has not, however, alleged a "representative sample" or even an "instance of submission." *Bledsoe,* 501 F.3d at 509–10; *Barrett,* 251 F.Supp.2d at 35. Nor has the relator alleged that a specific physician or hospital submitted a false claim. *Willard,* 336 F.3d at 385. Instead, the relator relies only on the allegation that the defendants extensively promoted the FlexView system. The relator has identified no basis to relax the Rule 9(b) pleading standard because the alleged activities extended over years.

Even under a relaxed pleading standard, the relator must still state a factual basis for her assertions. *See United States ex rel. King v. Alcon Labs., Inc.,* 232 F.Supp.2d 568, 572 (N.D.Tex.2005) (finding that even under a relaxed pleading standard, the relators failed to plead fraud with particularity because the relator did not identify a single person involved in the alleged fraud, did not did not identify

specific fraudulent claims, and did not identify a single date on which fraudulent activity occurred); *United States ex rel. Lam v. Tenet Healthcare,* 481 F.Supp.2d 673, 688 (W.D.Tex.2006) (finding that even under a relaxed pleading standard, the relators failed to set forth a factual basis for their beliefs because they failed to name one physician who violated the anti-referral statute; did not specifically identify one fraudulent transaction; and failed to specifically allege the fraud's "when" by alleging only that the fraudulent events occurred "at some point in the 1980s, between 1995 and 2002, and in 1999). *Cf. Rost,* 507 F.3d at 732–33 (recognizing that Rule 9(b) may be satisfied where "although some questions remain unanswered, the complaint as a whole is sufficient to pass muster under the FCA," but upholding dismissal because the relator did not identify specific physicians who submitted claims for reimbursement for off-label prescriptions).

**C. The Case Law on Off–Label Marketing as an FDA Claim**

Recently, a number of *qui tam* actions alleging FCA violations caused by off-label marketing by drug companies have been filed in federal courts.[12] Both parties discuss three such cases: *United States ex rel. Franklin v. Parke—Davis,* 147 F.Supp.2d 39 (D.Mass.2001); *United States ex rel. Hess v. Sanofi—Synthelabo Inc.,* No. 4;05CV570MLM, 2006 WL 1064127 (E.D.Mo. Apr.21, 2006); *Hopper v. Solvay Pharms. Inc.,* 588 F.3d 1318 (11th Cir.2009). *In addition, both parties discuss In re Cardiac Devices Qui Tam Litig.,* a *qui tam* case alleging FCA violations caused by unlawful use of medical devices by hospitals. 221 F.R.D. 318 (D.Conn.2004).

***18** In *Franklin v. Parke—Davis,* the relator, a doctor formerly employed by Parke—Davis to promote its drug Neurotonin, alleged that Parke—Davis engaged in a "fraudulent scheme to promote the sale of the drug Neurotonin for 'off-label uses' ... and that this illegal marketing campaign caused the submission of false claims to the Veterans Administration and to the federal government for Medicaid reimbursement." 147 F.Supp.2d at 43. The FDA approved Neurotonin "for use as an adjunctive treatment for epilepsy in doses from 900 to 1800 mg per day." *Id.* at 45. The relator alleged that Parke—Davis promoted Neurotonin for off-label use "as mono-therapy for epilepsy, for control of bipolar disease, and as treatment for attention deficit disorder." *Id.* Parke—Davis's alleged off-label promotional tactics included using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke—Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke—Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no scientific value." *Id.* at 45–46.

The relator also alleged that "when questions arose concerning the availability of reimbursement for prescriptions for off-label uses of Parke—Davis drugs," Parke—Davis made efforts to conceal the fraud. *Id.* at 46. Medical liasons "were instructed to coach doctors on how to conceal the off-label nature of the prescription" and Parke—Davis "shredd[ed] documents, falsif[ied] documents, and encourag[ed] medical liaisons to conduct their marketing activities without leaving a paper trail." *Id.*

Parke—Davis moved to dismiss. Unlike the medical device case in which there is FDA approval for general use related to the specific purpose being promoted, there was no dispute as to whether "an off-label prescription submitted for reimbursement is a false claim within the meaning of the FCA." *Id.* at 51. The court granted Parke—Davis's motion in part and denied it in part. *Id.* at 44.

The court found that the complaint met Rule 9(b)'s pleading requirements with respect to submissions to Medicaid because it sufficiently alleged fraudulent schemes to "increase the submission of off-label prescriptions for Neuortonin for payment by Medicaid" and "to induce off-label prescriptions for Neurotonin" by physicians. *Id.* at 48. It reasoned that the relator identified the fraud's "who" by naming Parke—Davis employees who instructed medical liaisons on how to fraudulently promote off-label use of Neurotonin, listing the medical liaisons by name, and identifying the physicians contacted; identified the fraud's "what" by alleging that the off-label promotion resulted in the submission of ineligible claims for reimbursement for off-label use of Neurtonin; identified the fraud's "when" by alleging the term of the relator's employment; and the fraud's "how" by alleging a detailed description of the marketing scheme that included "misleading" materials *Id.* The relator also alleged eleven "specific examples of fraudulent statements which medical liaisons ... were trained to give to physicians, and did give to physicians, to induce the purchase of Neurotonin for off-label uses." *Id.* In contrast, the court found that the complaint did not sufficiently allege a fraudulent scheme to cause false submissions to the Veterans Administration because it did not "specify which Parke—Davis personnel engaged in this conduct, where such conduct took place, which VA personnel

were involved, or any specific fraudulent statements made to personnel at the [VA].” *Id.* at 50.

***19** With respect to the Medicaid allegations, the court rejected Parke—Davis's causation challenges. Parke—Davis argued that the FCA does not impose liability for violating FDA regulations because such violations do not involve a claim or statement to the government. The court stated:

> It is true that the FCA cannot be used to enforce compliance with every law or regulation ... the FCA can be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit.... Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a).

*Id.* at 51–52 (internal citations omitted). The court also rejected Parke—Davis's argument that off-label promotion does not always entail a false statement. Parke—Davis argued that off-label promotion may involve only the distribution of one physician's finding of new drug's use to another physician. The court responded that the relator alleged “more than a mere technical violation of the FDA” by alleging that physicians distributed findings they knew to be false. The court also rejected Parke—Davis's argument that physicians' independent determinations that an off-label prescription provided the best treatment for a patient cut off Parke—Davis's liability because it was an intervening cause. The court responded that because the intervening cause was foreseeable to Parke—Davis, the chain of causation did not break. *Id.* at 51–53. Finally, the court rejected Parke—Davis's argument that its false statements were not “material” to the government's decision to pay. The court noted that “[l]iability under the FCA ... is not limited only to false statements or claims made directly by the Defendant to the government,” and that the FCA “ ‘reaches beyond claims which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.’ ” *Id.* at 53 (citing *United States v. Neifert—White Co.,* 390 U.S. 228, 233, 88 S.Ct. 959, 19 L.Ed.2d 1061 (1968)).

However, the *Parke—Davis* court dismissed the relator's kickback allegations. The court rejected the relator's argument that a violation of the antikickback statute is a *per se* violation of the FCA. The court reasoned that though an FCA violation might be based on “ ‘implied certification’ [of compliance with the antikickback statute] by virtue of the defendant's participation in the federal program,” the relator had “failed to allege that physicians either expressly certified or, through their participation in a federally funded program, impliedly certified their compliance with the federal antikickback statute as a prerequisite to participating in the federal program.” *Id.* The court reasoned that “while Defendant's payment of kickbacks may well be illegal,” the relator did not allege that “Parke—Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute.” *Id.* at 55.

***20** In *Hess,* the relator alleged that Sanofi—Snythelabo's off-label promotion of its drugs Eloxatin—approved for “second line treatment of fourth stage colorectal cancer”—and Elitek—approved for the treatment and prevention of tumor lyses syndrome—caused the submission of false claims for payment for off-label uses. 2006 WL 1064127, at *2. The relator alleged that Sanofi—Synthelabo promoted Eloxatin for treatment in both “first-line” and “adjuvant”[13] settings by training sales representatives to use off-label data when promoting Eloxatin to physicians, creating sales goals impossible to meet without off-label usage, and by providing sales representatives with monographs containing information on adjuvant and first-line trials for Eloxatin. *Id.* at *8. The relator further alleged that the data provided to physicians was “immature, unreliable, and misleading.” *Id.* With respect to Elitek, the relator alleged that Sanofi—Synthelabo trained its sales representatives to promote off-label uses and pressured the sales representatives to derive a substantial number of sales from off-label use. *Id.* at *6. Sanofi—Synthelabo moved to dismiss. It argued that the relator did not allege any false representations to physicians or the government, did not allege any improper prescriptions, and did not allege that doctors who prescribed the drugs also sought reimbursement from Medicare. Sanofi—Synthelabo also argued that the relator failed to alleged fraud with the required particularity. *Id.* at *4. Specifically as to Eloxatin, Sanofi—Synthelabo argued that because Medicare does not require a physician to specify the stage of cancer in submitting claims for reimbursement, physicians made no false statements in submitting claims for use of Eloxatin to treat colorectal cancer in first-line and adjuvant settings. *Id.* at *8. The court granted Sanofi—Synthelabo's motion to dismiss, addressing the allegations involving each drug separately.

The court dismissed the allegations related to Elitek under Rule 9(b) because the relator failed to allege the “who, what,

when, where, and how of fraud." *Id* at *6. The court noted that the relator did not allege "the time or place of the allegedly false representations regarding Elitek," "the nature or content of claims made which were allegedly fraudulent," or "that doctors to whom Plaintiff promoted off-label use of Elitek actually submitted false claims to the Government for off-label uses of this prescription drug." *Id.* The court deemed the relator's allegations "vague" and "conclusory" and dismissed for "lack of the requisite specificity to withstand a motion to dismiss pursuant to either Rule 12(b)(6) or Rule 9(b)." *Id.*

The court also dismissed the Eloxatim allegations because the relator did not allege a "material" misrepresentation. In *United States ex rel. Costner v. United States,* the Eighth Circuit adopted a materiality requirement for FCA claims, requiring that the misrepresentation have the natural tendency to influence an agency action, the same test the Fifth Circuit adopted in *Longhi.* 317 F.3d 883, 887–88 (8th Cir.2003). The court accepted Sanofi—Synthelabo's argument that the reimbursement claims did not contain a material false statement because the reimbursement forms did not require that the physician indicate the stage of cancer, only that the patient had cancer. The only statement material to Medicare reimbursement is that the patient had cancer; the government does not inquire further into whether the drug is approved for a particular cancer stage. *Id.* at *7.

***21** The court considered other arguments. It agreed with Sanofi—Synthelabo's argument that the relator did not sufficiently plead the FCA's knowledge requirement because the plaintiff did not allege that the "Defendant deliberately lied nor that the data provided by Defendant either to its sales representatives or to doctors was incorrect or false." *Id.* at *9. The court distinguished the alleged promotion tactics in *Parke—Davis* by noting that "none of the actions which Plaintiff alleges on the part of the Defendant ... involve conduct which was designed to present *false* information; rather ... the Defendant sought to disseminate date and information from trials and studies." *Id.* at *10. The court found that the relator did not sufficiently allege false statements to Medicare. The court noted that while typically Medicare reimburses only on-label prescriptions, "such approval is not necessarily a requirement." *Id.* The court also noted that-unlike in *Parke—Davis*—the relevant Medicare administrator chose to apply an exception allowing coverage for off-label prescriptions of Eloxatin and concluded that "because ... the Medicare administrator included off-label uses of Eloxatin for reimbursement purposes, Plaintiff can prove no set of facts to establish that Defendant violated the FCA." *Id.* at *9. Finally, the court, applying *Parke—Davis,* found that the relator did not allege fraud with the particularity required by Rule 9(b). The court found that the complaint did not identify the fraud's "who" because it did not "identify doctors whom sales representatives allegedly contacted nor ... doctors who allegedly made claims for Medicare reimbursement for off-label uses" or the fraud's "how" because it did not provide "examples of the allegedly false information which Defendant allegedly gave its sales representatives." *Id.*

In *Solvay,* the relators alleged that Solvay Pharmaceuticals's off-label promotion of Marinol caused the submission of false claims for reimbursement to Medicare. 588 F.3d at 1321. The FDA approved Marinol, a synthetic form of THC, a hallucinogenic compound found in marijuana, for use as an appetite stimulant for AIDS patients and for the treatment of nausea and vomiting associated with cancer chemotherapy. *Id.* at 1322. The relators alleged that Solvay promoted Marinol for off-label treatment of appetite loss in cancer patients and of nausea in HIV patients. The alleged off-label promotional activities included "a sophisticated marketing plan" and "kickbacks to physicians and other healthcare providers to induce them to prescribe Marinol for off-label purposes." *Id.* at 1323. The district court referred the case to a magistrate judge, who recommended dismissal. The district court adopted the magistrate judge's recommendation and the relators appealed. *Id.* The issue on appeal was whether the complaint, "which did not include allegations of specific false claims or allege that Solvay intended for its statements to influence the government's decision to pay any claims, satisfies the particularity requirements of Rule 9(b)." *Id.*

***22** The Eleventh Circuit upheld the district court's dismissal. In reaching this conclusion, the Eleventh Circuit discussed its decisions in *United States ex rel. Clausen v. Lab Corp. of Am.,* 290 F.3d 1301 (11th Cir.2002); *United States ex rel. Corsello v. Lincare, Inc.,* 428 F.3d 1008 (11th Cir.2005); and *United States ex rel. Atkins v. McInteer,* 470 F.3d 1350 (11th Cir.2006). In *Clausen,* the court upheld the district court's dismissal of a complaint alleging the submission of claims for reimbursement for unnecessary laboratory tests even though the complaint "included detailed allegations of a scheme to overcharge, [ ] identified the patients who received tests, specified which tests were improper, and set forth the dates on which the tests were performed" because the complaint "failed to provide any information linking the testing schemes to the submission of false claims." *Solvay,* 588 F.3d at 1325 (citing *Clausen,* 290 F.3d at 1303). Absent an allegation linking the schemes to the submission of false

claims, the Eleventh Circuit found that the allegations were conclusory. *Id.* (citing *id.*). In *Corsello,* the court upheld the district court's dismissal of a complaint alleging that medical equipment companies engaged in a "kickback and referral scheme to falsify certificates of medical necessity to submit false claims for Medicare payments" because "it did not allege that a specific fraudulent claim was in fact to submitted to the government." *Id.* (citing *Corsello,* 428 F.3d at 1013–14). In *Atkins,* the court upheld the district court's dismissal of a complaint alleging "an elaborate scheme for defrauding the government by submitting false claims" for payments from Medicare for psychiatric services that were not actually rendered. *Id.* (citing *Atkins,* 470 F.3d at 1354). The complaint cited "particular patients, dates and corresponding medical records for services" not eligible for reimbursement. *Id.* (citing *id.* at 1359). In upholding the dismissal, the *Atkins* court reasoned that the relator "failed to provide the next link in the [FCA] liability chin: showing that the defendant *actually submitted* reimbursement claims for the services he described." *Id.* (quoting *id.*). The *Solvay* court noted that unlike *Clausen, Corsello,* and *Atkins,* the complaint contained "a highly-detailed compelling statistical analysis [that] rendered inescapable the conclusion that a huge number of claims for ineffective uses of Marinol resulted from [Solvay's illegal marketing] campaign." *Id.* at 1326. Nonetheless, the court upheld the dismissal because it did not "allege the existence of a single actual false claim." *Id.* Under these precedents, the *Solvay* court upheld the district court's dismissal because the relators did not allege "the actual presentment of a false claim." *Id.* at 1324.

The *Solvay* court also found the allegations insufficient under Rule 9(b) because they did not "identify specific persons or entities that participated in any step of the process. Nor [did] it allege dates, times, or amounts of individual false claims." *Id.* And, even assuming that "when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription be borne by the federal government," the allegations were still insufficient because the complaint did not "identify a single physician who wrote a prescription with such knowledge; did not "identify a single pharmacist who filled such a prescription"; and did not "identify a single state healthcare program that submitted a claim for reimbursement to the federal government." *Id.* The court summarized: "We cannot conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering 'some indicia of reliability ... of an actual false claim for payment being made to the government.' " *Id.* (citing *Clausen,* 290 F.3d at 1311 (emphasis removed)).

Finally, the *Solvay* court distinguished the allegations from those found sufficient in *United States ex rel. Walker v. R & F Properties of Lake Co., Inc.,* 433 F.3d 1349 (11th Cir.2005). In *Walker,* the complaint "included allegations of first-hand knowledge that explained why [the relator] believed a specific defendant submitted false or fraudulent claims"; under the facts alleged in *Solvay,* by contrast, "the relators [did] not allege personal knowledge of the billing practices of any person or entity." *Solvay,* 588 F.3d at 1325 (discussing *Walker,* 433 F.3d at 1360).

***23** *In re Cardiac Devices* discussed an FCA claim based on off-label use of a medical device. Unlike the present suit, that case involved the pre–1995 Medicare regulations that prohibited reimbursement for devices the FDA did not approve for marketing. 221 F.R.D. at 326–27. A sales representative for cardiovascular-device manufacturers alleged that 132 clinical-trial hospitals from thirty states submitted Medicare reimbursement claims for services involving "nearly sixty different investigational cardiac devices that had not been approved for marketing by the [FDA]" in direct contravention of the manual instructions.[14] *Id.* at 332. After receiving notice of the complaint, the Office of the Inspector General of HHS subpoenaed records from the hospitals and ultimately elected to intervene. *Id.* at 327. The government and the relator moved to sever the action against each hospital and to transfer each to the federal district where the hospital was located. *Id.* at 327. The separate complaints for each hospital generally alleged that the hospitals received cardiac devices the FDA had not approved pursuant to an "Investigation Device Exemption" that restricted their use to "carefully monitored clinical trials ... to gather evidence of the safety and effectiveness of the devices." *Id.* at 329. The complaints alleged that the hospitals had submitted reimbursement claims to Medicare and Medicaid for using the devices in treatment and received "millions of dollars in Medicare and Medicaid reimbursements." *Id.* at 330. The complaints broke "down the number of procedures performed involving each particular cardiac device." *Id.* For example, the complaint for one hospital stated "that it charged Medicare and/or Medicaid for at least thirty-seven procedures involving prosthetic heart valves manufactured by St. Jude that had not received marketing approval from the FDA." *Id.* The complaints also alleged that the defendant hospitals "were on notice ... that Medicare considered medical procedures involving cardiac devices that had not been approved for marketing by the FDA ... to be non-covered and non-reimbursable" and that the hospitals knowingly misrepresented the devices' approval in

claims for reimbursement sent to their respective Medicare intermediaries. *Id.*

The defendants filed two motions to dismiss the complaints. The first motion argued that the complaints did not allege fraud with sufficient particularity. Specifically, the defendants argued that:

(1) the complaints merely allege a "per se" fraud theory, equating fraud with an alleged violation of the Medicare Hospital Manual and not particular fraudulent misconduct;

(2) the complaints do not identify specific claims submitted to the government and do not allege the "who, what, when, where, and why" of the defendants' allegedly fraudulent misconduct; and

(3) the complaints do not allege facts giving rise to a strong inference of fraudulent intent.

***24** *Id.* at 331.

In denying the defendant's motion to dismiss, the court first held that the plaintiffs were entitled to a relaxed pleading standard because the alleged fraud involved a "complex scheme" with numerous transactions and "the specific factual information" was peculiarly within the defendants' control. *Id.* at 333–34. By contrast, no such relaxation is warranted under the Fifth Circuit case law. As discussed, the pleading standard is not relaxed when such information is available from third party entities and individuals. *Rafizadeh,* 553 F.3d at 873 n. 6. The record shows that in the present case, the defendants do not have billing or reimbursement information; doctors, hospitals, and government agencies do.

The court in *In re Cardiac Devices* rejected the defendant's first argument, that violation of the manual provision's "reasonable and necessary" requirement is only a regulatory violation and not fraud *per se.* The court found that a physician's certification that the use of the device was "reasonable and necessary" was an "underlying condition to payment." *Id.* at 335–36. The court also found that the complaints alleged specific false submissions by the hospitals, including the "who, what, where, when, and how" of the alleged fraudulent statement.[15] The court cited the Eleventh Circuit's decision in *United States ex rel. Clausen v. Lab Corp. of Am.,* which upheld dismissal of an FCA complaint because the relator did not allege "an actual false claim." 290 F.3d at 1311. The *Cardiac Devices* court noted that the complaints "listed the number of claims" for each device and included "patient lists" provided by the defendant hospitals that, when read in conjunction, "identified the submission of specific claims." *Id.* at 337. The court distinguished *Clausen:*

> This is not a situation where only a general scheme of fraud was alleged that might have resulted in the submission of false claims. Here, the fraudulent scheme was the submission of the claims themselves. This stands in sharp contrast to the complaints in Clausen, which "[a]t most, ... raise[d] questions about [the defendant's] internal testing policies. But nowhere in the blur of facts and documents assembled by Clausen regarding six alleged testing schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." 290 F.3d at 1312.

*Id.* Finally, the court found that the complaints alleged facts giving rise to a strong inference of fraudulent intent. Because the FCA requires only that a defendant act "knowingly," the complaints do not to allege "a specific intent to defraud." *Id.* at 339. Instead, complaints had to allege " 'the knowing presentation of what is known to be false' as opposed negligence or innocent mistake." *Id.* (citing *Mikes v. Straus,* 274 F.3d 687, 703 (2d Cir.2001) (citing *Hagood v. Sonoma County Water Agency,* 81 F.3d 1465, 1478 (9th Cir.1996), *cert. denied,* 519 U.S. 865, 117 S.Ct. 175, 136 L.Ed.2d 116 (1996))).

***25** The defendants' second motion to dismiss argued that the complaints failed to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6) because they did not allege that the claims were "false or fraudulent." *Id.* at 342. The court first determined that hospitals' requests for payments on form HCFA–1450 (UB–82[16] and UB–92) "clearly constituted the submission of a 'claim' " under the FCA. *Id.* at 343. The court also found that annual Cost Reports the hospitals submitted were claims because they were accompanied by certifications that the reports were "true, correct, and complete and prepared in accordance with applicable instructions." *Id.* at 344. The court held that the allegations of false claims were sufficient under the Second Circuit's approach in *Mikes v. Straus,* 274 F.3d 687 (2d Cir.2001). The court explained:

> The Second Circuit in *Mikes* held that a claim may satisfy the falsity element of the FCA in one of three ways. It may be factually false if it "incorrectly describes the goods or services provided or a request for goods or services never provided," [274 F.3d at 697, or it may be legally false because of an express false certification or

an implied false certification. *Id.* at 697–98. In *Mikes,* the Second Circuit held an "expressly false claim is ... a claim that falsely certifies compliance with a particular statute, regulation or contractual terms, where compliance is a prerequisite to payment." *Id.* at 698 (emphasis added). Under an implied false certification theory, the act of submitting a claim for reimbursement itself implies compliance with the governing federal rules that are a precondition to payment. *Id.* at 699 (emphasis added). The Court emphasized that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the [FCA] may properly be found therefore when a defendant submits a claim for reimbursement while knowing—as that term is defined by the Act, see 31 U.S.C. § 3729(b)—that payment expressly is precluded because of some noncompliance by the defendant."

*Cardiac Devices,* 221 F.R.D. at 345. The court found that the claims were alleged to be false under the "factually false" and "legally false/expressly false certification" theories. The claims were alleged to be factually false because the forms instructed hospitals "to enter any remarks not shown elsewhere on the bill but which were necessary for proper payment" and to list "[n]on-covered charges." *Id.* The hospitals' failure to state that the procedures performed were experimental, which were non-covered charges, made the claims factually false. The court also found that the claims were "legally false" because "42 U.S.C. § 1395y(a)(1)(A) contains an express condition of payment—'no payment may be made [under Medicare] for any expenses incurred for items or services which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury,' " and that it " 'explicitly links each Medicare payment to the requirement that the particular item or service be 'reasonable and necessary.' " *Id.* (quoting *Mikes,* 274 F.3d at 700). The court found that the alleged claims falsely certified compliance and that the certification of compliance was a prerequisite for payment. *Id.* at 346. For the same reasons, the court found that hospitals' certifications on annual Cost Reports that the reports were "true, correct, and complete" falsely certified compliance where compliance was a prerequisite for payment." The court stated:

> ***26** The Medicare regulations imposed on defendants the obligation to provide the intermediaries with all information necessary to determine whether payment was due. Critical to this determination would be information concerning whether services were provided for a non-covered item ...
>
> ... [I]n submitting their claims, defendants were obligated to seek payment only for those services that were covered. To the extent that they sought payment for services that were not covered, the claims were legally false. The Government has alleged in its complaints that defendants knowingly submitted claims for payment of non-covered services provided in connection with investigational devices that were not reasonable and necessary. These FCA causes of action, as pled, set forth sufficient facts to satisfy the third element, that the claims were false or fraudulent.

*Id.* at 347.

## IV. Analysis

### A. The Allegations that the Defendants Violated the FCA by Marketing a Medical Device for Off–Label Use

The relator alleges that the defendants' off-label promotion of the FlexView system for the treatment of atrial fibrillation caused physicians and hospitals to submit claims to the government falsely stating that the use of the FlexView system was "reasonable and necessary" or "medically necessary." *See, e.g., Mikes,* 254 F.3d at 700–01 (finding that HCFA–1500 forms implicitly certify that requests for reimbursement comply with 42 U.S.C. § 1395y(a)(1) (A)'s requirement that the items and services provided were "reasonable and necessary"). The relator's claim is that the use of the FlexView system for treating atrial fibrillation cannot be medically necessary because it is not FDA approved for such use. *See* (Docket Entry No. 75, at 11) ("Defendants' entire surgical ablation marketing scheme is rendered fraudulent by the absence of FDA approval (and indeed the presence of express FDA disapproval) for the *single specific* use being promoted, namely the use of surgical ablation to treat atrial fibrillation.").

Importantly, there is no allegation that the defendants concealed or misstated the limits of the FDA's approval on the use of the FlexView system. The relator alleges only off-label promotion efforts, including direct training to physicians on using the FlexView system to treat atrial fibrillation, instructions to salespersons to promote FlexView off-label, and promotional materials highlighting the economic benefits to hospitals of treating atrial fibrillation with Flexview.[17] There is no allegation that the defendants represented that the FlexView system was FDA-approved to treat atrial fibrillation. *Compare Parke—Davis,* 147 F.Supp.2d at 46

(describing Parke—Davis's efforts to conceal the lack of FDA approval).

Unlike the Medicare coverage at issue in *In re Cardiac Devices,* Medicare may cover medically necessary uses of the FlexView system. Medicare contractors may approve coverage for Category B devices. 42 C.F.R. § 405.211(b). The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients. The cases recognize that off-label use of a drug or medical device is distinct from a medically unnecessary use of that drug or device. *See Buckman,* 121 S.Ct. at 1018; *Polansky,* 2009 WL 1456582, at *6; *Svidler,* 2004 WL 2005781, at *5; *Stephens,* LEXIS 2009 DIST. 101601, at *20. For medical devices like the FlexView system, the relator must allege sufficient facts to support an inference that the use of the device is not "medically necessary" or "reasonable and necessary" under Medicare regulations. The relator acknowledges this in her brief. (Docket Entry No. 75, at 10).

***27** The relator cites *United States ex rel. Riley v. St. Luke's Episcopal Hosp.,* 355 F.3d 370, 376 n. 6 (5th Cir.2004), in which the court stated that submitting a request for payment "certifies" that "the services shown on the [payment] form were medically indicated and necessary for the health of the patient." *See also* 42 U.S.C. § 13957(1)(A) ("[N]o payment may be made ... for any expenses ... which ... are not reasonable and necessary for the ... treatment of illness or injury...."). The relator also points to 42 U.S.C. § 1320c–5(a)(3)'s statement that:

> It shall be the obligation of any health care practitioner ... who provides health care services for which payment may be made ... to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients of this chapter ... will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

These authorities state that a procedure must be "medically necessary" but do not further define the term. The authorities cited by the relator do not provide a basis to infer that a reimbursement submission for using the FlexView system to treat atrial fibrillation, even as a stand-alone procedure, cannot be medically necessary or reasonable and necessary because it is not specifically approved for that purpose.

The relator argues that the use of the FlexView system for surgical treatment of atrial fibrillation is by definition not medically necessary because it is viewed as experimental within the scientific community. But Medicare may cover Class II devices even though they "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. § § 405.201(b), 405.211(b). *Cf.* 42 CFR § 405.209 (stating that "payment under Medicare for a non-experimental/investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA"). The State's Medicare carrier determines "the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 58, ¶ 65). The relator does not allege that *any* state has denied coverage for surgical ablation to treat atrial fibrillation, whether as a stand-alone treatment or in connection with other cardiac procedures. Alleging that the use of the FlexView system to treat atrial fibrillation is "experimental" does not allege a basis for an inference that such use of the system is categorically medically unnecessary.

Nor does the relator allege specific false statements by the defendants that the FlexView system is a first-line treatment for atrial fibrillation. The relator alleges that the defendants promoted FlexView to treat atrial fibrillation even though the FDA had not approved this use and emphasizes that the defendants' salespersons trained physicians to use the FlexView system despite the lack of FDA approval for the specific use of treating atrial fibrillation. These are not statements that the FlexView system is a first-line treatment for atrial fibrillation or that it was FDA approved to treat atrial fibrillation and do not support an inference that the defendants caused physicians and hospitals to submit reimbursement claims for using the FlexView system as a first-line treatment for atrial fibrillation.

***28** In addition, the relator has failed to plead with sufficient particularity the alleged false claims. The relator has not identified specific physicians or hospitals who received the promotions. She has not alleged the "who" or "where" of the alleged fraud. *See, e.g., Thompson,* 125 F.3d at 903. Like the allegations involving false submissions to the Veterans Administration the *Parke—Davis* court dismissed, but unlike the allegations involving Medicaid submissions the court did not dismiss, the relator has not identified any specific physicians who received off-label promotion. *Parke—Davis,*

147 F.Supp.2d at 48. Nor has the relator identified any physician to whom the defendants promoted FlexView off-label and who also "actually submitted false claims to the Government for off-label uses" of FlexView. *Hess,* 2006 WL 1064127, at *6; *see also Solvay,* 588 F.3d at 1326 (upholding the district court's dismissal because the relators "did not identify specific persons or entities that participated in any step of the process"); *Polansky,* 2009 WL 1456582 (E.D.N.Y. May 22, 2009) (dismissing *qui tam* involving off-label promotion of Lipitor because the plaintiff did not identify any false claims or physicians who were induced to write a prescription for an off-label use). *Compare Cardiac Devices,* 221 F.R.D. at 337 (denying a motion to dismiss where the complaint identified specific hospitals and specific fraudulent claims). These allegations do not plead fraud with the particularity required by the Fifth Circuit's decision in *Thompson.*

The relator argues that the Eleventh Circuit's decision in *Solvay* is inconsistent with the Fifth Circuit's decision in *Grubbs* because *Solvay* relies on *Clausen* and the Fifth Circuit rejected *Clausen'* s holding that "the minimum indicia of reliability required to satisfy the particularity standard are the specific contents of actually submitted claims." *Grubbs,* 565 F.3d at 186 (citing *Clausen,* 290 F.3d at 1311). But the *Solvay* court did not apply *Clausen'* s rule that the complaint must allege the specific contents of an actually submitted false claim. Instead, *Solvay* upheld the district court's dismissal because the relator did not allege "the existence of a single false claim ... let alone a false or fraudulent claim." 588 F.3d at 1326.

In *Grubbs,* the court recognized that the Eleventh Circuit has "moved away from *Clausen'* s most exacting language, accepting less billing detail in a case where particular allegations of a scheme offered indicia of reliability that bills were presented." 565 F.3d at 187 (citing *Walker,* 433 F.3d at 1360). But the relator has not alleged the type of information that the *Grubbs* relator did. The Fifth Circuit explained in *Grubbs:*

> The complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud. Grubbs describes in detail, including the date, place, and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot. He alleges his first-hand experience of the scheme unfolding as it related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred. Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill.

***29** *Id.* at 191–92. Under *Grubbs, Thompson,* and other precedents, the relator's complaint does not sufficiently allege that by promoting off-label use, the defendants caused the submission of false claims and are liable under the FCA.

The relator has alleged a number of unlawful promotional tactics. The cases recognize that even if a drug or device manufacturer's marketing or promotion activities violate FDA regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement. *See Rost,* 507 F.3d at 732; *Hess,* 2006 WL 1064127, at *6; *Polansky,* 2009 WL 1456582, at *7. In *Parke—Davis,* the relator identified Parke—Davis's unlawful promotional tactics, including using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke—Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke—Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no scientific value." 147 F.Supp.2d at 45–46. The relator also provided eleven "specific examples of fraudulent statements which medical liaisons ... were trained to give physicians, and did give to physicians." *Id.* at 48. The court still dismissed the relator's allegations covering the submission of claims to the Veterans Administration for failure to identify "which Parke—Davis personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the VA." *Id.* at 50. Similarly, in *Rost,* the relator alleged that Pharmacia promoted Genotropin off-label through cash payments for off-label studies, rebates and other kickbacks for off-label prescriptions, and off-label marketing materials. 507 F.3d at 723–24. The relator also alleged statistical data demonstrating a likelihood of high volume off-label prescription-writing. *Id.* at 732. The appellate court nonetheless upheld the dismissal:

> It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

*Id.*

In this case, under *Grubbs* and other precedents, the allegations are both insufficient and insufficiently particularized. The claims of an FCA violation by off-label promotion are dismissed, with leave to amend.

**B. The Allegations on Upcoding**

The relator alleges that the defendants instructed hospitals and physicians to "upcode" stand-alone surgical ablations —minimally invasive, closed-chest procedures—by entering the code associated with open-chest procedures, ICD–9 procedure code 37.33, in reimbursement claims. The relator alleges that physicians and hospitals should have entered procedure code 37.99, which is more appropriate for such minimally invasive procedures. The relator alleges that entering code 37.33 instead of code 37.99 generates a significantly higher Medicare reimbursement and that the defendants' sales representatives "coached hospitals to obtain over-reimbursement of nearly $20,000, or 300% higher than the hospital cost of the procedure each time Defendants' microwave surgical ablation system is used as a stand-alone procedure." (Docket Entry No. 58, ¶ 121). The relator alleges that the defendants' sales presentations highlighted favorable reimbursement rates and identified code 37.33 as the appropriate code for stand-alone surgical ablations, not code 37.99. Because there was an economic incentive to "upcode," because the defendants pointed out the opportunity to do so, and because stand-alone ablation procedures were presumably performed, the relator argues that she has alleged a sufficient basis to support an inference that the defendants caused hospitals to "upcode" and submit false claims to Medicare.

***30** Under the applicable case law authority, the relator has not pleaded this scheme to defraud with sufficient particularity to withstand dismissal. The relator has not identified any hospital or physician who did in fact "upcode" improperly in a Medicare reimbursement submission. These allegations fail to allege information about the "who, what, when, where, and how of the alleged fraud." *Thompson,* 125 F.3d at 903. And although the Fifth Circuit qualified the "time, place, and contents" requirement in *Grubbs,* the relator's complaint in this case is still deficient.

The cases involving FCA upcoding allegations against physicians support this result. In *United States ex rel. Bledsoe v. Cmty. Health Sys.,* a district court dismissed a relator's allegations that a hospital submitted numerous false claims for reimbursement to Medicare and Medicaid. 501 F.3d 493 (6th Cir.2007). The appellate court upheld the dismissal even though the relator identified the CPT codes incorrectly entered in reimbursement submissions because the allegations did "not meet the minimum standard of the 'time, place and content of the alleged misrepresentation on which [the injured party] relied.' " *Id.* at 513 (citing *United States ex rel. Bledsoe v. Cmty. Health Sys.,* 342 F.3d 634, 643 (6th Cir.2003)). While the relator in this case has alleged codes physicians and hospitals should use in submitting claims for reimbursement for minimally invasive, stand-alone surgical ablation procedures, the relator has not identified any physicians or hospitals that put the incorrect code on a Medicare reimbursement claim. These allegations are insufficient under the applicable case law.

In *United States ex rel. Atkins v. McInteer,* 470 F.3d 1350 (11th Cir.2006), the allegations included upcoding. The relator alleged that the defendants submitted claims for, and received, Medicare reimbursement for psychiatric services that were: "(1) not rendered, (2) not medically necessary, (3) the result of improper 'upcoding,' (4) grounded in psychiatric evaluations provided by unqualified staff personnel, (5) based upon 'pre-formed,' predetermined sets of patient evaluations, diagnostic codes, and treatment plans, and (6) provided with substandard levels of care." *Id.* at 1354. The Eleventh Circuit affirmed the district court's dismissal, stating that "the complaint fails rule 9(b) for want of sufficient indicia of reliability to support the assertion that the defendants submitted false claims." *Id.* at 1358–59. Even though the relator cited particular patients, dates, and corresponding medical records for services he contended were not eligible for government reimbursement, his claim failed because he did not allege facts showing that the defendants actually submitted reimbursement claims for the services he described. "Instead, he portrays the scheme and then summarily concludes that the defendants submitted false claims to the government for reimbursement." *Id.* at 1359.[18] The relator argues that she has alleged "a definite narrative of the motive, strategy, and results of the Defendants' ... scheme...." (Docket Entry No. 75, at 25). But in the complaint, the relator has not cited "particular patients, dates, and corresponding medical records" for the alleged upcoding. Nor has the relator alleged that any physician or hospital submitted a false claim for reimbursement. These allegations do not plead fraud with the particularity required by Rule 9(b).

***31** One other point is worth noting. Procedure codes and DRGs are part of Medicare's Prospective Payment System (PPS). One court has explained PPS as follows:

> Under PPS, hospitals are reimbursed based on a pre-determined rate for each Medicare admission. The rate depends on each patient's particular diagnosis and other clinical information. Each patient is classified into a Diagnosis Related Group (DRG) that determines the amount of payment. The DRG payment amounts were derived based on average costs incurred in treating particular conditions. By paying a flat rate based on the patient diagnosis, the PPS system gives providers a financial incentive to provide cost-efficient care.

*United States ex rel. Digiovanni v. St. Joseph's/Candler Health Sys.,* 2008 WL 395012, at *6 (S.D.Ga. Feb.8, 2008) (citing 42 C.F.R. § 412.2(f); Health Care Financing Administration, 65 Fed.Reg. 18434–01 (April 7, 2000); American Hospital Directory, Medicare Prospective Payment System, http:// www.ahd.com/pps.html (last visited Nov. 19, 2007)). The PPS is designed to provide an incentive to hospitals to use lower-cost procedures to treat the diagnosis identified in the PPS code. The allegation that the defendants encouraged hospitals to use the FlexView system in part because of the opportunity to profit by performing a lower-cost procedure to treat the diagnosis does not create a reasonable inference that physicians and hospitals knowingly submitted false claims. There must be an allegation that the defendants and the hospitals and physicians knew that using the DRG code 37.3 3 for stand-alone minimally invasive surgical ablations was always incorrect and that code 37.99 was the only correct code. The complaint fails to state a claim for relief.

**C. The Allegations that the Defendants Paid Kickbacks**

The relator alleges that the defendants provided remuneration in various forms to hospitals and physicians to induce them to purchase and use the FlexView system, in violation of the antikickback statute, 42 U.S.C. § 1320a–7b(b)(1–2). The relator alleges that compliance with the antikickback statute is a prerequisite to seeking reimbursement under Medicare and that a false certification of compliance is a basis for a claim under the FCA. *See Thompson,* 125 F.3d at 902; *Graves,* 284 F.Supp.2d at 497. The Fifth Circuit has held that payment of Medicare claims may be "conditioned upon certification of compliance with laws and regulations including the anti-kickback statute." *Id.; see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 20 F.Supp.2d 1017, 1041–42 (S.D.Tex.1998) (finding on remand that allegations that the defendant expressly certified compliance with the antikickback statute in annual cost reports sufficiently states a claim under the FCA because the certifications were a condition of retaining Medicare payments made during the prior year and a condition of continued eligibility for the Medicare program).

***32** The antikickback statute provides:

> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof,
>
> shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a–7b(b)(1–2).

The facts alleged by the relator are insufficient under the applicable case law to state a claim under the certification theory of FCA liability. The cases demonstrate that the

basis of liability is the certification of compliance, not the payment or acceptance of remuneration. *See Siewick,* 214 F.3d at 1376–77 (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *Willard,* 336 F.3d at 382–83 (upholding district court's dismissal because the plaintiff only alleged violations of HMO enrollment antidiscrimination laws but did not allege that the United States "conditioned payment ... on any implied certification of compliance with the anti-discriminatory provisions"); *Roop,* 559 F.3d at 824 (upholding district court's dismissal because the plaintiff alleged only violation of FDA medicaldevice-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

The relator alleges that the defendants paid unlawful remuneration to hospitals and physicians for their use of the FlexView system, that physicians and hospitals accepted the remuneration, and that physicians and hospitals made reimbursement claims to Medicare. However, the relator has not alleged that the defendants caused any physicians or hospital to make false certifications of compliance. In *Parke—Davis,* the relator's failure to make this allegation warranted dismissal. *See* 147 F.Supp.2d at 55 (noting that the relator did not allege that "Parke—Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute"). Because the relator has not alleged that the defendants caused any hospital or physician to certify compliance with the antikickback statute, these allegations are dismissed.[19]

***33** Even if the relator sufficiently alleged that the defendants' kickbacks caused false certifications, the relator has not provided reliable indicia that physicians or hospitals actually falsely certified compliance. The relator has not identified the " 'who, what, when, where, and how' " the alleged false certifications. *See Lam,* 481 F.Supp.2d at (citing *Thompson,* 125 F.3d at 903). The relator has not identified a physician or hospital falsely certifying compliance with the antikickback statute in applying for Medicare reimbursement for surgical ablation using the FlexView system; when such a false certification was made; or how such a false certification was made. Instead, the relator has alleged different types of remuneration provided by the defendants and identified certain hospitals and doctors performing stand-alone surgical ablations. These allegations do not provide reliable indicia that there were actual false certifications of compliance. *See id.* at 687 (dismissing allegations of false certifications of compliance with antikickback statute even though the relators named the "who" because the relators did not allege "even one specific illegal referral" or the specific times of the fraud); *Carpenter,* 723 F.Supp.2d at 405 (dismissing allegations of an off-label pharmaceutical kickback scheme because the relator could not "offer any particulars as to names, dates, amounts, or the incentives doctors are alleged to have been offered"); *United States ex rel. Kennedy v. Aventis Pharms.,* 610 F.Supp.2d 938, 945 (2009) (the relators "identified a number of hospitals to which Aventis allegedly gave kickbacks disguised as unrestricted grants to induce their continued use and/or promotion of Lovenox for unapproved indications," but failed to allege "that one or more of the hospitals falsely certified, in connection with a Medicare claim, that it had complied with the anti-kickback statute; the failure to identify "any certification by a hospital," caused dismissal). The relator fails to identify any hospitals or physicians who certified compliance with the antikickback statute. These allegations are dismissed.

**D. The Retaliation Allegations**

The relator alleges that the defendants retaliated against her for challenging the legality of their marketing practices by firing her. She asserts that this violated both section 3730(h) of the FCA and Illinois law. Section 3730(h), the FCA's antiretaliation provision, states:

> Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

***34** The *prima facie* elements of a retaliation claim under the False Claims Act are that: (1) the employee engaged in protected activity under the statute; (2) the employer knew that the employee engaged in protected activity; and (3) the employer discriminated against the employee because she engaged in protected activity. *Graves,* 284 F.Supp.2d 487, 510 (S.D.Tex.2003), *aff'd,* 111 F. App'x 296 (5th Cir.2004)

Similarly, Illinois law recognizes a tort for "retaliatory discharge." *Zimmerman v. Buchheit of Sparta, Inc.,* 164 Ill.2d 29, 206 Ill.Dec. 625, 645 N.E.2d 877, 880 (Ill.1994). "A plaintiff states a valid claim for retaliatory discharge only if she alleges that she was (1) discharged; (2) in retaliation for her activities; and (3) that the discharge violates a clear mandate of public policy." *Id.*

The relator's complaint does not allege sufficient factual allegations for either her FCA or Illinois retaliation claims. *Cuvillier,* 503 F.3d at 401. For both claims, the relator alleges only that she "challenged the legality of the Defendants' ... marketing techniques both during her initial training and during a national sales meeting" and that she "was reprimanded, harassed and discharged by Defendants as a direct cause of her acts challenging Defendants' marketing approach as unlawful." (Docket Entry No. 58, ¶¶ 127–28). Courts have held that such threadbare recitations of the elements of an FCA retaliation claim do not meet Rule 12(b)(6)'s pleading standard. *See United States ex rel. Davis v. Prince,* 2010 WL 2679761, at *4 (E.D.Va. July 2, 2010) (dismissing FCA retaliation claim when the plaintiff only alleged that "the defendants wrongfully terminated [the relator] for seeking to rectify the abuses occurring in the Jordan offices").[20] Nor do threadbare recitations of the elements of an Illinois retaliation claim meet Rule 12(b)(6)'s pleading standard. *See Fleszar v. Am. Med. Ass'n,* 2010 WL 1005030, at *9 (N.D.Ill. Mar.11, 2010) (dismissing complaint because the plaintiff alleged only that she "was discharged ... in retaliation for her reporting perceived violations of state and federal law to ... management and to state and federal agencies"); *United States v. Thorek Hsp. and Med. Ctr.,* 2007 WL 2484333, at *1 (N.D.Ill. Aug.29, 2007) (dismissing as conclusory allegations that the plaintiff refused to assist doctors to create claims she believed to be false and that she was fired because of her refusal). The relator's allegations do not state a claim for relief under the FCA or Illinois law.

The relator argues that an Illinois district court's decision in *Jones v. Park Forest Coop. IV,* No. 09–C–2653, 2010 WL 748147 (N.D.Ill. Feb.26, 2010), establishes that allegations that a plaintiff complained about an activity and was discharged plausibly states a claim for relief for retaliatory discharge under Illinois law. In *Jones,* the plaintiff's complaint contained factual allegations. The court, citing the plaintiff's complaint, wrote:

> ***35** On December 12, 2006, Tas completed an allegedly false disciplinary report of plaintiff. (*Id.* ¶ 18.) On December 15, 2006, plaintiff complained to Tas about being unfairly disciplined when Sandy Isaac, a bookkeeper employed by the defendant whose job duties included making the health benefit plan payments to the insurance carrier, had not been disciplined for her failure to pay the insurance carrier in a timely manner. (*Id.* ¶¶ 13, 22 .) Plaintiff openly demanded reimbursement for out-of-pocket medical expenses incurred as a result of the failure to pay the healthcare insurance premiums. (*Id.* ¶ 61b-c.)
>
> Plaintiff alleges that Isaac, who reported directly to Tas, sought to persuade Tas to terminate plaintiff due to his complaints and his assertion of racial discrimination. (*Id.* ¶¶ 25–26.) After December 15, 2006, plaintiff received false, adverse, work-related performance reports made to justify his subsequent termination. (*Id.* ¶ 23.) In April and May 2007, Tas issued plaintiff official warnings of imminent termination for substandard performance. (*Id.* ¶¶ 44–45.) Shortly thereafter, Tas terminated plaintiff. (*Id.*).

*Id.* at *1. These allegations provide far more detail than the relator's complaint. *Jones* does not provide a basis to deny the defendants' motion to dismiss.

The relator also cites three Illinois appellate court decisions to support her contention that allegations that the plaintiff complained and was discharged state a plausible claim for relief. In both cases, the court applied the "fair notice" pleading standard rejected in *Twombly* and *Iqbal. See Sherman v. Kraft Gen. Foods, Inc.,* 272 Ill.App.3d 833, 209 Ill.Dec. 530, 651 N.E.2d 708, (Ill.App.Ct.1995) ("Dismissal of a cause of action on the pleadings is only proper where it is clearly apparent that plaintiff can prove no set of facts that would entitle him to recover."); *Paskarnis v. Darien—Woodridge Fire Protection Dist.,* 251 Ill.App.3d 585, 191 Ill.Dec. 138, 623 N.E.2d 383, 586 (Ill.Ct.App.1993) (same); *Russ v. Pension Consultants Co., Inc.,* 182 Ill.App.3d 769, 131 Ill.Dec. 318, 538 N.E.2d 693, 696 (Ill.Ct.App.1989) (same). These cases are inapplicable.

The FCA and Illinois retaliation claims are dismissed.[21]

**E. Leave to Amend**

The relator requested leave to amend should this court dismiss their complaint. (Docket Entry no. 75). The relator has only amended once, (Docket Entry No. 58), before the filing of the defendants' motion to dismiss. This court grants the relators leave to amend. *See Great Plains Trust Co.,* 313 F.3d at 329; *Adrian,* 363 F.3d at 403. An amended complaint must be filed by April 15, 2011.

**V. Conclusion**

The defendants' motion to dismiss, (Docket Entry No. 68), is granted, without prejudice. The relator may amend her complaint by April 22, 2011,

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Footnotes

1 31 U.S.C. § 3729 *et seq.*

2 A private person may bring an FCA action in the name of the government. 31 U.S.C. § 3730(b). The complaint is served on the government under Federal Rule of Civil Procedure 4(d)(4) and filed *in camera* and under seal for at least sixty days. *Id.* at § 3730(b)(1). The government may elect to intervene and proceed with the action within sixty days after it receives both the complaint and the material evidence and information. *Id.* The relators did not file evidence or information beyond the complaint in this case.

3 The other qui tam actions are discussed in this court's opinion in *United States ex rel. Bennett v. Medtronic, Inc.*, —— F.Supp.2d ——, 2010 WL 3909447 (S.D.Tex. Sept.30, 2010). This opinion uses much of the analysis from this court's previous opinion.

4 *See generally,* Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail,* 61 FOOD AND DRUG L.J. 653, 655–56 (2006).

5 Under the FDCA, new pharmaceuticals cannot be distributed in interstate commerce unless the drug's sponsor satisfies the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Once a drug is approved for a particular use, the FDA does not prevent doctors from prescribing the drugs for uses that are different than those approved by the FDA. *Parke—Davis,* 147 F.Supp.2d 39, 44 (D.Mass.2001) (citing *Buckman,* 121 S.Ct. at 1018). However, "[w]hether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program." *Id.* One court has summarized the drug-reimbursement criteria, as follows:

> Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* § 1396r–8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. *Id.* § 1396r–8(k)(6). *See also id.* § 1396r–8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

*United States ex rel. Franklin v. Parke—Davis,* 147 F.Supp.2d 39, 44–45 (D.Mass.2001).

6 At the time of the third amended complaint, Boston Scientific was engaged in a study about the FlexView system's efficacy in the treatment of atrial fibrillation. The study is called "RESOLVE–AF" (Randomized Study of Surgical Ablation with Microwave Energy for the Treatment of Atrial Fibrillation). (Docket Entry No. 58, ¶ 77).

7 The relator's upcoding allegations appear to be directed at hospitals. (Docket Entry No. 58, ¶ 116). In describing Medicare billing procedures, the amended complaint alleges that hospitals use ICD–9–CM codes for billing, (*Id.,* ¶ 27) and that physicians use CPT codes, (*Id.,* ¶¶ 29–33, 37). The upcoding allegations appear to be focused on the upcoding of the ICD–9–CM code entered by the hospitals. (*Id.,* ¶ 118).

8 In *Longhi,* the Fifth Circuit did not state whether this four-prong test applies to the version of the FCA amended by 31 U.S.C. § 3729(a)(1)(B), the "post—FERA version." For post-FERA claims, the fourth prong—that the statement "cause the government to pay out money or forfeit money"—may need alteration. The post-FERA FCA does not require that the government actually pay the false claim. *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who ... knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim *paid or approved by the government.")* (emphasis added); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who ... knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). The application of pre- and post-FERA versions of the FCA is analyzed below, but the elements of a false statement, scienter, and materiality are unaffected. 31 U.S.C. 3729(a)(1)(A–B).

9 The relator also alleged that the defendants violated 31 U.S.C. § 3729(a)(7), *amended by* 31 U.S.C. § 3729(a)(1)(G). Section 3729(a)(7) establishes liability for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." In their briefing, the relator appears to focus on allegations involving sections (a)(1) and (a) (2) and does not argue that section (a)(7) demands a different analysis. Though this opinion refers explicitly only to (a)(1) and (a)(2), its analysis is applicable to (a)(7) to the extent the relator asserts (a)(7) provides a basis for liability.

10 Some courts have held that FERA's retroactivity clause is unconstitutional. *E.g., United States ex rel. Sanders v. Allison Engine Co., Inc.,* 667 F.Supp.2d 747, 755 (S.D.Ohio 2009) (finding that application of the retroactivity clause violates the Constitution's Ex Post Facto Clause, U.S. CONST. art. 1, § 9, cl. 3). The Fifth Circuit has not ruled on this issue. *See United States ex rel. Longhi v. Lithium Power Techs., Inc.,* 575 F.3d 458, 470 (5th Cir.2009) (declining to rule on whether FERA applies retroactively). Neither party raised this issue and it is not necessary to address because the result is the same under either the pre-or post-FERA version of the FCA.

11 As the analysis makes clear, in this litigation, there is no material difference between pre- and post-FERA versions of § 3729(a) (1). FERA removed § 3729(a)(1)'s requirement that the claim be presented "to an officer or employer of the United States Government or a member of the Armed Forces of the United States." *Compare* 31 U.S.C. § 3729(a)(1), *amended by* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who ... knowingly presents or causes to be presented, *to an officer or employee of the United States government or a member of the Armed Forces of the United States,* a false or fraudulent claim for payment or approval." (deleted language italicized)); *with* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). The defendants do not contest that the reimbursement claims were presented to the government. Similarly, the differences between the pre- and post-FERA versions of § 3729(a)(2) do not affect this litigation. FERA removed § 3729(a)(2)'s requirement that the alleged false claim be "paid or approved by the government." *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who ... knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government."); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who ... knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). The defendants do not dispute that the government paid or approved the reimbursement claims. FERA also added a materiality requirement to § 3729(a)(2). *See* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who ... knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false fraudulent claim") (emphasis added). This change does not affect this litigation because the Fifth Circuit required "material" false statements before the FERA amendments to § 3729(a)(2). *United States ex rel. Longhi v. Lithium Power Techs., Inc.,* 575 F.3d 458, 470 (5th Cir.2009). And the post-FERA version of § 3729(a)(2) and the Fifth Circuit both use the same test for materiality. 31 U.S.C. § 3729(b) (4) ("[M]aterial means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."); *Longhi,* 575 F.3d at 470 (adopting the "natural tendency test," which only requires "that the false or fraudulent statements have the potential to influence the government's decisions," and noting the test's consistency with FERA).

12 *See* Richard C. Ausness, *There's Danger Here, Cherie!: Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-label Uses,* 73 Brook. L.Rev.. 1253, 1275–96 (2008) (identifying the FCA as a source of liability for off-label promotion and discussing recent cases).

13 An "adjuvant" use of a drug is a use to "enhance the effectiveness of" other medical treatment. Webster's Ninth New Collegiate Dictionary 56 (Merriam–Webster 1990).

14 A number of the defendant hospitals settled before the court's decision on the motion to dismiss. *Cardiac Devices,* 221 F.R.D. at 326–27.

15 The complaints alleged "who" by identifying the specific hospitals; "what" by identifying the specific claims submitted; "where" as the place where the claims were filed; "when" by providing the "dates of the patients' hospitalizations" or the year annual cost reports were filed; and "how" by detailing the Medicare reimbursement scheme. *Clausen,* 209 F.3d at 337.

16 UB–82 forms were used until 1994, when they were replaced by UB–92 forms. *See Cardiac Devices,* 221 F.R.D. at 345.

17 The relator argues that an FDA warning letter sent to St. Jude Medical establishes that the defendants misrepresented the scope of FDA approval. (Docket Entry No. 75, Ex. A). The letter admonishes St. Jude for the off-label promotion of surgical ablation to treat atrial fibrillation. It does not reference Boston Scientific or Guidant. The complaint does not allege that Boston Scientific or Guidant misrepresented the scope of FDA approval to doctors or hospitals. The FDA warning letter does not provide a basis to deny the defendants' motion to dismiss.

18 Similar results were reached in *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.,* 251 F.Supp.2d 28, 35 (D.D.C.2003) (dismissing FCA upcoding allegations because the complaint did not sufficiently "link" the upcoding allegations "with the submission of claims to Medicare"); *United States v. Aggarwal,* No. 6:03–cv–117–Orl–31KRS, 2005 WL 6011259, at *6 (M.D.Fla. Feb.10, 2005) (dismissing FCA upcoding allegations against a physician because the United States failed to allege that claims were filed in connection with a specific procedure performed and also failed to allege "the names of the patients in whose name claims were filed, claim numbers, the dates of such claims, to whom the claims were made, and what any of the Defendants received as a result"). *Compare United States ex rel. Harris v. Bernard,* 275 F.Supp.2d 1, 6 (D.D.C.2003) (denying a motion to dismiss because the relator identified the employees who caused the submission of false claims; pleaded that the fraud began in 1993 and continued to the time of lawsuit; pleaded that the fraud occurred in the defendant's offices; pleaded twelve "sample patients" whose claims did not correspond with their treatment; and pleaded that the defendants provided treating physicians with fee tickets allowing physicians to select only high paying codes).

19 As noted, the Fifth Circuit has not adopted implied certification as a theory of FCA liability. *Marcy,* 520 F.3d at 389 (citing *Willard,* 336 F.3d at 381–82); *Southland Mgmt. Corp. .,* 326 F.3d at 679 (Jones, J. concurring); *Steury,* 625 F.3d at 268. The relator can state a claim that "the defendant has made a false certification of compliance with the statute or regulation, when payment is conditioned on that certification." *Graves,* 284 F.Supp.2d at 497; *Steury,* 625 F.3d at 269. Whether the relator alleges that the defendants expressly or impliedly certified compliance with the antikickback statute is unclear. The relator alleges: "Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations." (Docket Entry No. 58, ¶ 44). The relator does allege that violation of the antikickback statute can cause exclusion from Medicare, but she does not allege any specific certification of compliance. (*Id.* at ¶ 43). *Compare Cardiac Devices,* 221 F.R.D. at 345 (identifying the forms on which the compliance certifications were made, where the forms required certification, and the false statements of certification).

20 Courts have also held that to prevail on an FCA retaliation claim, the plaintiff must do more than "challenge" the defendant; she "must have specifically investigated or complained about the employer making false claims for federal funds, and the employee must show that the employer knew of the investigation or complaint." *See Bouknight v. Houston Ind. Sch. Dist.,* 2008 WL 110427, at *4 (S.D.Tex. Jan.8, 2008); *United States v. Columbia Healthcare Corp.,* 2005 WL 1924187, at * 13 ("In addition, the protected conduct element requires that a whistleblower must report or investigate attempts to defraud the government."); *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.,* 251 F.Supp.2d 28, 38 (D.D.C.2003) (nothing that the FCA retaliation provision requires that "an employee be investigating false or fraudulent claims aimed at extracting money from the government." (citing *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1269 (9th Cir.1996); *Hammack v. Automated Info. Mgmt., Inc.,* 981 F.Supp. 993, 996 (N.D.Tex.1997)); *Luckey v. Baxter Healthcare Corp.,* 2 F.Supp.2d 1034, 1055 (N.D.Ill.1998) ("[T]he employee must, at least to some degree, couch her concerns or investigation in terms of funds her employer fraudulently obtained from the government.").

21 The defendants also moved to dismiss the relator's Illinois retaliation claims on the basis that the complaint alleges insufficient contacts with that state to justify the application of Illinois law. As the defendants acknowledge in their brief, the complaint contains insufficient facts to resolve this issue.

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# APPENDIX B

2017 WL 1209909
Only the Westlaw citation is currently available.
United States District Court,
S.D. Texas, Houston Division.

Guerdon GREEN, et al, Plaintiffs,
v.
AMERISOURCEBERGEN CORPORATION, et al, Defendants.

Civil Action No. 4:15–CV–379
|
Signed 03/31/2017

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**MEMORANDUM OPINION AND ORDER**

Kenneth M. Hoyt, United States District Judge

**I. Introduction**

***1** Pending before the Court is the defendants', AmerisourceBergen Corporation, Cardinal Health, Inc., and McKesson Corporation (collectively the "defendants") Joint Motion to Dismiss Relator's Third Amended Qui Tam Complaint pursuant to Rules 12(b)(1), 12(b)(6), 8(a) & 9(b) of the Federal Rules of Civil Procedure (Dkt. No. 45) and Memorandum in Support (Dkt. No. 46). The Relator, Guerdon Green ("Relator"), filed a response in opposition (Dkt. No. 52), to which the defendants filed a reply (Dkt. No. 55). After having carefully reviewed the motions, the responses and the applicable law the Court GRANTS the defendants' joint motion to dismiss.

**II. Factual Background**

The following allegations are found in the Relator's Third Amended Qui Tam Complaint ("Complaint"). The Relator joined Syntegra Solutions, Inc. ("Syntegra") in 2003 as the Vice President of Sales and Marketing. The current Complaint asserts that Syntegra was retained by manufacturers to audit the defendant wholesalers. Syntegra conducted two main auditing functions: chargeback audits and operational audits. While at Syntegra, Relator managed corporate relationships and conducted closing meetings at the conclusion of each audit. *See* (Dkt. No. 19 at 7). The Relator alleges that through his work at Syntegra the Relator uncovered the fraudulent acts of the defendants.

Pursuant to the *qui tam* provisions of the Federal False Claims Act ("FCA"), 31 U.S.C. § 3730, Relator filed the initial complaint in this action on or about February 9, 2015, filed an amended complaint on or about March 9, 2015, and filed the Complaint on or about January 5, 2016. Relator completed service of the Complaint and the disclosure statement required by 31 U.S.C. § 3730(b)(2) on the Attorney General and the United States Attorney's Office for this District. On November 9, 2015, the United States declined to intervene, as did each State named in the first two complaints.

In his Complaint, the Relator alleges that the defendants—three large pharmaceutical wholesalers—engaged in conduct that caused drug manufacturers to underpay rebates owed to Medicaid pursuant to the Medicaid Drug Rebate Program ("MDRP"), 42 U.S.C. § 1396r–8. Under the MDRP, drug manufacturers are required to calculate the Average Manufacturer Price ("AMP") for each of their outpatient drugs covered by Medicaid, report those AMPs to the Centers for Medicare and Medicaid Services ("CMS") on a quarterly basis, and pay quarterly rebates to State Medicaid programs that based, in part, on the reported AMPs. The AMP for each covered drug is generally based on the average unit price manufacturers receive from wholesalers (or after passage of the Affordable Care Act in 2010, from wholesaler and retail pharmacies purchasing directly from manufacturers) during the relevant time period, net of discounts and other price concessions that lower the amounts actually paid for the drug.

The conduct at issue in this case relates to "chargebacks," which are payments that drug manufacturers make to wholesalers when the wholesalers are contractually required to sell the manufacturers' drugs to their retail customers at special reduced prices pursuant to contracts between the manufacturers and retailers. The Relator's Complaint alleges that the defendants submitted and continue to submit false data to manufacturers in the form of the 844 Data Set. The Relator argues that the accuracy of the 844 Data Set is important to manufacturers because the information within this Data Set is used to calculate AMP. Relator claims that the comparison of the 844 Data Set to the 867 Data Set exposed the defendants' fraudulent activities.

***2** The Relator further alleges that the defendants violated the FCA by engaging in four types of misconduct associated with chargebacks: (1) failing to issue "reverse chargebacks" to the drug manufacturers when retailers returned drugs for which the defendants had previously received chargeback payments from the manufacturers; (2) submitting duplicate chargeback requests to the manufacturers; (3) refusing to issue reverse chargebacks to the manufacturers when the amounts due do not exceed a threshold amount, or when the customer returns occur after a threshold period of time; and (4) submitting fraudulent chargeback requests. Relator contends that each of these improper practices artificially affected the net amounts the drug manufacturers received for sales of their products, causing the manufacturers to calculate and report artificially reduced AMPs to CMS, thereby causing the manufacturers to underpay MDRP rebates due to State Medicaid programs, and further causing the United States to be overcharged for payments to the State Medicaid programs.

## III. Contentions of the Parties

### A. The Defendants' Contentions

The defendants have moved to dismiss the Relator's claims. The defendants aver that Relator's Complaint fails to state a claim on which relief can be granted, and it fails to satisfy the heightened pleading standard required for FCA claims. The defendants further allege the following arguments. First, Relator's allegations are based on and are substantially the same as prior publicly available information and, thus, the public-disclosure bar precludes his claims. Second, Relator's theory of liability rests on a fundamental misreading of the applicable statute and regulations concerning the calculation of AMP. Third, the Complaint fails to satisfy Rules 8 and 9(b) of the Federal Rules of Civil Procedure because Relator does not plead a plausible factual basis for relief, i.e. requisite scienter, and particular facts demonstrating the existence of fraudulent action. Accordingly, the defendants argue that their motion to dismiss should be granted.

### B. The Relator's Contentions

The Relator alleges that from 2004 to the present, the defendants fraudulently concealed and withheld chargeback payments from the manufacturers, causing the manufacturers to underreport AMP. The Relator argues that the defendants' fraudulent activities caused the manufacturers to commit fraud against the federal government. The Relator alleges that his Complaint clearly satisfies the Rule 9(b) standard promulgated by the Fifth Circuit requiring "particular details" of a fraudulent scheme and "reliable indicia" that false claims were presented. The Relator argues that the defendants' public disclosure defense is not applicable, arguing that the defendants' "public disclosures" fail to qualify as public disclosures under both guidelines set by the Fifth Circuit as well as 31 U.S.C. § 3730(e)(4)(A)(ii) and (iii). Finally, the Relator asks that the Court deny the defendants' motion to dismiss.

## IV. Standard of Review

### A. Rule 12(b)(1)

" '[A] challenge under the FCA jurisdictional bar is necessarily intertwined with the merits' and is, therefore, properly treated as a motion for summary judgment." *U.S. ex rel. Reagan v. E. Texas Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 173 (5th Cir. 2004) (quoting *Laird,* 336 F.3d at 352). "A grant of summary judgment is proper if, viewing the evidence and inferences drawn from that evidence in the light most favorable to the non-moving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Id.* (citing Fed.R.Civ.P. 56(c)). At the summary judgment stage, a court may not weigh the evidence or evaluate the credibility of witnesses, and all justifiable inferences will be made in the non-moving party's favor. *Morris v. Covan Worldwide Moving, Inc.*, 144 F.3d 377, 380 (5th Cir.1998).

Federal Rule of Civil Procedure Rule 12(b)(1) permits the dismissal of an action for the lack of subject matter jurisdiction. "If [a federal] court determines at any time that it lacks subject-matter jurisdiction, [it] must dismiss the action." Fed. R. Civ. P. 12(h)(3). Because federal courts are considered courts of limited jurisdiction, absent jurisdiction conferred by statute, they lack the power to adjudicate claims. *See, e.g.,*

  

*Stockman v. Fed. Election Comm'n*, 138 F.3d 144, 151 (5th Cir. 1998) (citing *Veldhoen v. United States Coast Guard*, 35 F.3d 222, 225 (5th Cir. 1994). Therefore, the party seeking to invoke the jurisdiction of a federal court carries "the burden of proving subject matter jurisdiction by a preponderance of the evidence." *Vantage Trailers, Inc. v. Beall Corp.*, 567 F.3d 745, 748 (5th Cir. 2009) (citing *New Orleans & Gulf Coast Ry. Co. v. Barrois*, 533 F.3d 321, 327 (5th Cir. 2008);*see also Stockman*, 138 F.3d at 151.

***3** When evaluating jurisdiction, "a [federal] court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *MDPhysicians & Assoc., Inc. v. State Bd. of Ins.*, 957 F.2d 178, 181 (5th Cir. 1992) (citing *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981)); *see also Vantage Trailers*, 567 F.3d at 748 (reasoning that "[i]n evaluating jurisdiction, the district court must resolve disputed facts without giving a presumption of truthfulness to the plaintiff's allegations.") In making its ruling, the court may rely on any of the following: "(1) the complaint alone, (2) the complaint supplemented by undisputed facts evidenced in the record, or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *MDPhysicians*, 957 F.2d at 181 n.2 (citing *Williamson*, 645 F.2d at 413).

**B. Rule 12(b)(6) and Rule 9(b)**

Federal Rule of Civil Procedure 12(b)(6) authorizes a defendant to move to dismiss for "failure to state a claim upon which relief may be granted." Fed. R. Civ. P. 12(b)(6). Under the demanding strictures of a Rule 12(b)(6) motion, "[t]he plaintiff's complaint is to be construed in a light most favorable to the plaintiff, and the allegations contained therein are to be taken as true." *Oppenheimer v. Prudential Sec., Inc.*, 94 F.3d 189, 194 (5th Cir. 1996) (citing *Mitchell v. McBryde*, 944 F.2d 229, 230 (5th Cir. 1991)). Dismissal is appropriate only if, the "[f]actual allegations [are not] enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 1965, 167 L. Ed.2d 929 (2007). Moreover, in light of Federal Rule of Civil Procedure 8(a)(2), "[s]pecific facts are not necessary; the [factual allegations] need only 'give the defendant fair notice of what the...claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93, 127 S. Ct. 2197, 2200, 167 L. Ed.2d 1081 (2007) (per curiam) (quoting *Twombly*, 550 U.S. at 555, 127 S. Ct. at 1964). Even so, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555, 127 S. Ct. at 1964–65 (citing *Papasan v. Allain*, 478 U.S. 265, 286, 106 S. Ct. 2932, 92 L. Ed.2d 209 (1986)).

More recently, in *Ashcroft v. Iqbal*, the Supreme Court expounded upon the *Twombly* standard, reasoning that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949, 173 L. Ed.2d 868 (2009) (quoting *Twombly*, 550 U.S. at 570, 127 S. Ct. at 1974). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556, 127 S. Ct. at 1955). "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show [n]'-'that the pleader is entitled to relief.' " *Iqbal*, 556 U.S. at 679, 129 S. Ct. at 1950 (quoting Fed. R. Civ. P. 8(a)(2)). Nevertheless, when considering a 12(b)(6) motion to dismiss, the Court's task is limited to deciding whether the plaintiff is entitled to offer evidence in support of his or her claims, not whether the plaintiff will eventually prevail. *Twombly*, 550 U.S. at 563, 127 S. Ct. at 1969 n.8 (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed.2d 90 (1974)); *see also Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999).

***4** Federal Rule of Civil Procedure 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other condition of mind of a person may be alleged generally." *Id*. Although the particularity Rule 9(b) demands differs with each case, "a plaintiff pleading fraud must set forth the who, what, when, and where before access to the discovery process is granted. Anything less fails to provide defendants with adequate notice of the nature and grounds of the claim." *Hart v. Bayer Corp.*, 199 F.3d 239, 248 n. 6 (5th Cir.2000) (quotations and citations omitted); accord *United States ex rel. Steury v. Cardinal Health, Inc. (Steury II)*, 735 F.3d 202, 204 (5th Cir.2013). Rule 9(b) has four purposes: to ensure that the defendant has sufficient information to formulate a defense by having notice of the conduct complained of; to protect defendants against frivolous suits; to eliminate fraud actions in which all the facts are learned after discovery; and to protect defendants from undeserved harm to their goodwill and reputation. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776,

783 (4th Cir.1999). Rule 9(b) must be interpreted and applied in light of these purposes.

" '[C]laims brought under the FCA must comply with the particularity requirements of 9(b)' for claims of fraud." *Steury II*, 735 F.3d at 204 (quoting and altering *United States ex rel. Steury v. Cardinal Health, Inc. (Steury I)*, 625 F.3d 262, 266 (5th Cir.2010)). While FCA claims must comply with Rule 9(b)'s pleading requirements, [i]n contrast to common-law fraud, the FCA "lacks the elements of reliance and damages." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 189 (5th Cir.2009). "It is adequate to allege that a false claim was knowingly presented regardless of its exact amount; the contents of the bill are less significant because a complaint need not allege that the Government relied on or was damaged by the false claim." *Id*.

"[T]o plead with particularity the circumstances constituting fraud for a False Claims Act [§ 3729(a)(1)(A) ] claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id*. at 190. To plead with the requisite particularity a § 3729(a)(1)(B) claim, the complaint need not "allege details of fraudulent bills actually presented to the government." *Id*. at 192. The relator must, however, allege facts showing that "the defendant made a false record or statement [material to] a false or fraudulent claim paid by the Government." *Id*.; *see* also 31 U.S.C. § 3729(a)(1)(B).

## V. Analysis and Discussion

### A. Federal False Claims Act

The FCA imposes monetary liability on any person who knowingly presents a false claim for payment to the federal government or knowingly makes a false statement material to a false claim. *See* § 3729(a)(1). The FCA authorizes private individuals to bring actions on behalf of the United States to enforce its provision, [§ 3730(b)]; however, it bars certain private actions that involve publicly disclosed allegations, [§ 3730(e)(4) (the "public disclosure bar") ]. On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act ("PPACA"), Pub.L. No. 111–148, 124 Stat. 119. Section 10104(j)(2) of this legislation replaces the prior version of 31 U.S.C. § 3730(e)(4) (2006) with new language. The prior version of the public disclosure bar and original source-requirement provided that:

> (4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of information.
>
> ***5** (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(A)–(B) (2006), amended by 31 U.S.C. § 3730(e)(4)(A)–(B) (Supp.2011). The PPACA amended the statute to currently read:

> (4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4)(A)–(B) (Supp.2011).

Because the Relator's allegations of fraud against the defendants extend from 2004 to present, *see* (Dkt. No. 19, at 4), the Court must apply the jurisdictional pre-PPACA version of the public-disclosure bar to the allegations of fraud that pre-date July 22, 2010. For Relator's allegations that post-date July 22, 2010, the Court must apply the non-jurisdictional public-disclosure bar.[1] The purpose of this jurisdictional bar is to accommodate the primary goals of the False Claims Act: (1) "promoting private citizen involvement in exposing

fraud against the government" and (2) "preventing parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud." *U.S. ex. rel. Laird v. Lockheed Martin Eng'g & Sci. Servs., Co.*, 336 F.3d 346, 351 (5th Cir. 2003). Accordingly, the Court will first address Relator's claims based on the defendants' conduct before July 22, 2010, under the old version of the statute.

**B. Pre–PPACA Amendment**

The Fifth Circuit employs a burden shifting framework when determining if there has been a public disclosure. First, the court asks "whether [Relator's] action was based upon public disclosures of allegations or transactions." *U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 327 (5th Cir. 2011). If the defendants identify public disclosures, the relator then has the burden to show a genuine issue of material fact as to whether his action was based on those public disclosures. *Id*. When determining if a public disclosure exists the Court must consider three questions: "(1) whether there has been a 'public disclosure' of allegations or transactions, (2) whether the qui tam action is 'based upon' such publicly disclosed allegations, and (3) if so, whether the Relator is the 'original source' of the information." *Id*. at 352. The Court does not have to rigidly follow these steps. *Id*. at 327. The Fifth Circuit has routinely combined the first step—public disclosure of allegations or transactions—and second step —that the action is based upon—of the analysis, focusing instead on whether the disclosures were related in scope to the Relator's complaint. *Id*.

***6** The defendants allege that Relator's claims have been publicly disclosed through news media and public comments to administrative proceedings. (Dkt. No. 46 at 18). The defendants' motion courses through Relator's claims and alleges evidence of public disclosures. *Id*. at 18–24. The defendants cited magazine articles, blog posts and newsletters, spanning from 2007 to 2010 that discussed discrepancies in chargeback data, duplicate chargebacks, and omitted reverse chargebacks as an issue for pharmaceutical manufactures. The defendants further allege public disclosures were made when CMS solicited comments on a proposed regulation and comments were filed by Teva Pharmaceuticals. Relator responds that the defendants failed to cite a qualifying public disclosure, arguing that Congress removed "administrative rulemaking proceeding" from the definition of public disclosure in 2010, which would disqualify the Teva comments, and that blogs do not qualify as "news media" under the public disclosure bar. Thus, the issue now turns on what constitutes a qualified public disclosure under the FCA.

As stated above, the Relator alleges that blogs do not constitute news media under 31 U.S.C. § 3730(e)(4)(A)(iii) and as such fail to qualify as a public disclosure. The Court does not agree. The Supreme Court has found that § 3730(e)(4)(A) is over-inclusive when determining if news media meets the standard of a public disclosure. "The 'news media' referenced in [§ 3730(e)(4)(A)(iii)] plainly have a broader sweep." *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 290, 130 S. Ct. 1396, 1404, 176 L. Ed. 2d 225 (2010). Courts have unanimously interpreted the term "public disclosure" to include websites and online articles. *See Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 408, 131 S.Ct. 1885, 179 L.Ed.2d 825 (2011). The defendants cited several magazines and blogs that meet this standard. More specifically, the defendants cite to an article found in a magazine named "Pharmaceutical Commerce" as well as several blog posts and newsletters published online by IDC Health. These articles discuss issues with chargeback payments and the resulting loss revenue suffered by manufactures. Founded in 2005, IDC Health provides market research and advisory services to health and life sciences industry executives. Distinguishable from cases cited by the Relator, the webpages cited by the defendants are easily available to the public and are updated on a regular basis. The Court is of the opinion that these disclosures are relevant and credible sources that are deemed "news media" in regards to § 3730(e)(4)(A)(iii).

Now the Court turns to the second prong of the test, which is to determine if the Relator's allegations were based on the defendants' public disclosure. It is the prevailing view of circuits that "a lawsuit is based upon publicly disclosed allegations when the relator's allegations and the publicly disclosed allegations are substantially similar." *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 915 (7th Cir. 2009). The Relator argues that the defendants' public disclosures are not substantially similar to his allegations, because the defendants' disclosures omitted significant facts needed to prove fraud. The Fifth Circuit has held that the test is satisfied if the complaint is "even partly based upon public allegations or transactions." *Stennett v. Premier Rehab., LLC*, 479 Fed.Appx. 631, 635 (5th Cir. 2012).

As stated above, the Complaint alleges that the defendants concealed reverse chargeback payments, submitted duplicate chargeback requests, and submitted fraudulent chargeback

requests, which caused underreported AMPs. These claims are substantially similar to those of a 2010 magazine article submitted by the defendants detailing lost revenue of the manufacturing companies due to the discrepancies between them and wholesalers in chargeback data, duplicate chargebacks, and omitted reverse chargebacks. (Dkt. No. 46, Tab. 52 at 5–6). The article goes on to mention the 867 Data Set, stating it is a "key data stream" that impacts all transactions between wholesalers and manufactures. *Id*. at 6. The Relator admits that the 867 Data Set played an integral part in uncovering the alleged fraud.

***7** The Relator argues further that the defendants' public disclosures fail to qualify because they do not match the scope or breadth of the Relator's claims and fail to provide allegations of Medicaid rebate fraud. This argument is unavailing as the Fifth Circuit has held that "[a]n FCA qui tam action even partly based upon public allegations or transactions is nonetheless 'based upon' such allegations or transaction[s]". *U.S. ex rel. Reagan v. E. Texas Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 176 (5th Cir. 2004). "A relator's ability to recognize the legal consequences of a publicly disclosed fraudulent transaction does not alter the fact that the material elements of the violation already have been publicly disclosed." *A–1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1245 (9th Cir. 2000).

Although the defendants' public disclosures may not match the Relator's claims exactly or detail the legal consequences of their actions, they are substantially similar and provide material elements of the Relator's claims. "An irreducible minimum is that the disclosures furnish evidence of the fraudulent scheme alleged." *Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 293 (5th Cir. 2012). The public disclosures produced by the defendants furnished evidence of actions that the Relator alleges to be fraudulent. They not only state the lost revenue as a result of the different chargeback payments, but they also reference the exact data set used to determine such loss. The manufactures were aware of the issues that plagued their industry; however, they just did not possess the technology to solve the issue. (Dkt. No. 46–5, Tab 60 at 47). Thus, the Court is of the opinion that the Relator has not met his burden of showing a genuine issue of material fact as to whether his action was based on the defendants' public disclosures.

**1. Original Source**

Since the Relator's complaint is based on public disclosures, it is barred unless he is an original source. *See* 31 U.S.C. § 3730(e)(4)(A). To be an original source, the Relator must have "direct and independent knowledge of the information on which the allegations are based," and must have "voluntarily provided the information to the Government before filing the qui tam action." *Reagan*, 384 F.3d at 177. The Relator alleges he provided the Attorney General of the United States and the United States Attorney for the Southern District of Texas, the information on which he bases the allegations prior to the filing of this suit. Thus, the issue is whether the Relator had direct or independent knowledge of the information.

The Relator does not have to "be an original source of every detail, [but] must have direct and independent knowledge of the core information underlying [the] allegations." *U.S. ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 782 F.Supp.2d 248, 277 (E.D.La. 2011). A relator's knowledge is "direct" if it is "derived from the source without interruption or gained by the relator's own efforts rather than learned second-hand through the efforts of others." *Laird*, 336 F.3d at 355. "In order to be 'direct,' the information must be firsthand knowledge." *See also U.S. ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 442 (5th Cir. 2008). The Fifth Circuit "requires independent knowledge of 'information on which the publicly disclosed allegations are based...' " *Reagan*, 384 F.3d at 178.

In this case, the Court finds that the Relator does not have direct and independent knowledge of the information on which the publicly disclosed allegations are based. By the Relator's own admission, he only learned of the defendants' activities through his years of experience in the pharmaceutical industry and the review of audits prepared by his company. (Dkt. No. 19 at 7). As held by the court in *Reagan*, the Fifth Circuit does not impute "direct and independent knowledge" to relators for simply contributing their own exploratory efforts and experience to develop allegations of fraud. *Reagan*, 384 F.3d at 179. Relator never claimed that he personally prepared the audits, but instead mistakenly claims that he qualifies as an original source because he "viewed source documents." (Dkt. No. 52 at 29). "[D]irect knowledge is obtained first hand, by the relator's own efforts rather than by the labor of others, and not derivative of the information of others." *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 287 Fed.Appx. 396, 400 (5th Cir. 2008) (internal quotations omitted). The fact that the Relator viewed the audits in "closing meetings" after they were completed, rather than compiling the information himself, would preclude him from securing "direct and independent knowledge" of the alleged fraud, as required by the Fifth Circuit.

***8** In conclusion, the Court finds that there has been a public disclosure of allegations and transactions on which the complaint is based and that Relator is not an original source. Thus, the public disclosure bar applies and this Court lacks jurisdiction over Relator's claims based on the defendants' conduct from 2004 through July 22, 2010. Accordingly, the defendants' motion to dismiss is **GRANTED**, which grant deems the defendants' remaining claims for dismissal moot.

**C. Post–PPACA Amendment**

The Court now addresses Relator's claims based on the defendants' conduct after July 22, 2010, under the PPACA–amended statute. Under the new statute, the Court finds that: 1) there has been a public disclosure of allegations or transactions; and 2) the Relator is not an original source. The 2010 amendment to the FCA amended the language "[n]o court shall have jurisdiction" to read "[t]he court shall dismiss an action or claim under this section, unless opposed by the Government." *Compare* 31 U.S.C. § 3730(e)(4)(A) (2006) with 31 U.S.C. § 3730(e)(4)(A) (Supp.2011). Thus, the Fifth Circuit no longer treats the public disclosure bar as a jurisdictional threshold, instead agreeing with other circuits. *See Abbott v. BP Expl. & Prod., Inc.*, No. 16–20028, 2017 WL 992506, at *2 (5th Cir. Mar. 14, 2017). Under the amended FCA statute, the first step remains the same, but the second step requires analysis of whether the publicly disclosed allegations or transactions are "substantially the same allegations or transactions as alleged in the action." *See* 31 U.S.C. § 3730(e)(4)(A) (Supp.2011). Accordingly, the Court combines these two steps in its analysis.

By combining the first two steps of the analysis, the issue fundamentally remains the same: whether the scope of Relator's action is similar to the allegations or transactions that are publicly disclosed. The only difference then involves the type of documents the Court may consider in determining whether allegations or transactions were publicly disclosed. *See* 31 U.S.C. § 3730(e)(4)(A) (Supp.2011) (mainly limiting available disclosures to news media and Federal sources). Even with this amended language, the Court finds that there has been a public disclosure in the sources that remain viable under the amended statute. For example, both the 2010 magazine article and the online blogs that discussed chargeback payments, 867 Data Sets, and lost revenue by the manufacturers, qualify as sufficient public disclosures under the amended statute. As previously discussed, these sources contain "allegations or transactions" that are related in scope to the Relator's claims. Therefore, the Court finds that there has been a public disclosure and this action must be dismissed, unless the evidence shows that Relator is an original source of the public disclosures.

**1. Original Source**

As previously stated, the Relator alleges to have properly notified the Government before filing his Compliant, which would constitute voluntary disclosure under the Act and thus satisfy the first prong of the "original source" provision: "(i) prior to a public disclosure under subsection (e)(4)(A), [an individual] has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based." 31 U.S.C. § 3730(e)(4)(A) (Supp.2011). As discussed above, there were other sources disclosed prior to the Relator's disclosure to the Government that constitute a public disclosure under subsection (e) (4)(A). For this and the reasons outlined above, the Court finds that this disclosure is not sufficient under the FCA's voluntary disclosure prong.

***9** The Court previously found that the Relator's knowledge was not independent of the publicly disclosed transactions. This finding is the same for conduct occurring after the amendment to the statute even considering that the amended statute limits the sources that may constitute publicly disclosed allegations or transactions. *See* 31 U.S.C. § 3730(e)(4)(A) (Supp.2011). Accordingly, the Relator is not an original source under the knowledge prong. In the alternative, the Court finds that the Relator failed to "have knowledge that ... materially adds to the publicly disclosed transactions" and thus, the Relator is not an original source.

The Relator alleges that through his work at Syntegra he was able to uncover information that materially adds to the public disclosures. More specifically, the Relator claims that his Complaint identified the allegations of the Medicaid rebate fraud on a national scale. (Dkt. No. 52 at 26). The defendants counter that "Relator's non-conclusory allegations do not "materially add" to these public disclosures as required by the statute, but merely provide additional background and illustrative examples of what had already been disclosed." (Dkt. No. 55 at 16).

"[The Court's] task is to ascertain whether the [relator's] allegedly new information is sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." *United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 211 (1st Cir. 2016). It is not a requirement that the defendants' public disclosures

explain every detail of the fraudulent activities so long as the disclosures reveal "essential elements" of the fraud. *See United States ex rel. Kraxberger v. Kan. City Power & Light Co.*, 756 F.3d 1075, 1079 (8th Cir.2014) (holding that a plaintiff's information did not materially add to the public disclosures because the disclosures already revealed " 'the essential elements comprising that fraudulent transaction...so as to raise a reasonable inference of fraud.' ").

Although the defendants' public disclosures do not specifically allege Medicaid fraud, the end result of these disclosures is one that naturally lead to the Relator's allegations. Moreover, knowledge of the alleged Medicaid fraud does not materially add to the allegations already publicly disclosed, but merely details a consequence of the disclosed actions. Accordingly, the Relator's knowledge does not "materially add" to the already disclosed allegations and, therefore, the Relator does not qualify as an "original source."

**VI. Conclusion**

In conclusion, the Court finds that Realtor does not qualify as an original source under either the voluntary disclosure prong or the knowledge prong of the statute. Thus, 31 U.S.C. § 3730(e)(4) (Supp.2011) requires Relator's claims, based on the defendants' conduct after July 22, 2010, to be dismissed. Accordingly, the defendants' joint motion to dismiss is GRANTED; the defendants' remaining claims are DENIED as moot. Based on the foregoing discussion, the Court **GRANTS** the defendants' motion to dismiss.

It is so **ORDERED**.

**All Citations**

Not Reported in Fed. Supp., 2017 WL 1209909

Footnotes

1 Although the post-PPACA version of the public-disclosure bar is not jurisdictional in nature, it expressly authorizes dismissal of an action or claim. 31 U.S.C. § 3730(e)(4)(A).

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# APPENDIX C

2016 WL 5661701
United States District Court,
S.D. Texas, Houston Division.

GREGORY G., et al., on behalf of United States, Plaintiffs,
v.
HOUSTON INDEPENDENT SCHOOL DISTRICT, Defendant.

CIVIL ACTION H-14-2768
|
Signed 09/30/2016

**Attorneys and Law Firms**

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**Memorandum Opinion and Order**

Gray H. Miller, United States District Judge

***1** Pending before the court is defendant Houston Independent School District's ("HISD") motion to dismiss Gregory G., Michelle G., Chad B., and Jill B., collectively "Relators," first amended complaint. Dkt. 19. The court has considered the motion, response, reply, and applicable law, and the court finds that HISD's motion to dismiss should be GRANTED and the claims should be DISMISSED WITH PREJUDICE.

## I. BACKGROUND

This case is a False Claims Act ("FCA") action, filed by Relators, alleging that HISD defrauded Medicaid. Dkt. 12. Relators allege that HISD submitted fraudulent claims on behalf of special education students under the Texas School Health and Related Services ("SHARS") program. Dkt. 12 at 2. SHARS coordinates with the state's Medicaid agency, the Texas Health and Human Services Commission, to provide Medicaid reimbursement for "health and related services that are determined to be medically necessary and reasonable to ensure a Medicaid-enrolled student with a disability receives a free appropriate public education." Dkt. 19 at 5. On September 28, 2014, Relators filed their original complaint alleging that, under the SHARS program, HISD tailored special education programs to provide medically unnecessary services for the purpose of maximizing Medicaid billing. Dkts. 1, 12. On December 5, 2015, Relators amended their original complaint to add allegations that HISD billed Medicaid for services not provided at all. Dkt. 12 at 5–7.

Relators allege that this scheme defrauded Medicaid of millions of dollars. Dkt. 12 at 6. Relators also allege that this scheme deprived Garrett G., Blake B., and other children their legally-entitled free and appropriate public education by tailoring special education programs to maximize billable services under Medicaid rather than based on educational needs. Dkt. 12 at 4. The U.S. government has declined to intervene in this *qui tam* action. Dkt. 5.

Relators Gregory G. and Michelle G. are the parents of Garrett G., a child with autism who was enrolled in HISD and received special education services "until September 2012 and then again for a brief period in September, 2013." Dkt. 12 at 1. Relators claim Garrett G. made little or no educational progress while enrolled in HISD. *Id.* A Hearing Officer also ruled that HISD failed to provide Garrett G. a free and appropriate public education required by the Individuals with Disabilities Education Act. *Id.* Relators allege that HISD's actions were a factor in Garrett G.'s poor educational progress because HISD tailored Garrett G.'s special education program to fraudulently bill for medically unnecessary services rather than for Garrett G.'s educational needs. *Id.*

Relators Chad B. and Jill B. are the parents of Blake B., a teenager with an autism spectrum disability who was enrolled in HISD and received special education services from 2005 to 2012. *Id.* at 5. Relators allege that HISD provided special education to Blake B. based on a characterization that he had an emotional disturbance coupled with Bipolar Disorder and ADHD-Severe until September 2012, when HISD added the autism spectrum disorder. *Id.* Relators claim that Blake B. was moved to a Behavior Support Classroom in 2007 with the expectation that he would transition out in approximately six months.[1] *Id.* However, Blake B. was kept in the classroom for four years and his education failed to advance beyond the fourth grade level he had achieved when he was originally placed in the classroom. *Id.* Relators claim keeping Blake B.

 

in a Behavior Support Classroom was unnecessary because Blake B. did not demonstrate the violent behaviors that justify this placement. *Id.* Relators claim HISD was motivated to keep Blake B. in the Behavior Support Classroom so that it could continue to bill the federal government for unspecified medically unnecessary services provided in that classroom. *Id.* at 5–6. Blake B.'s parents withdrew him from HISD in 2012. *Id.* at 6.

***2** Finally, Relators allege at least one special education teacher received instructions from HISD at Jeff Davis and Madison High Schools to bill for toileting and other special education services that were never provided. *Id.* at 7. Both Relators and HISD agree that this specific example was publically reported in the media prior to being included in the first amended complaint. Dkt. 19 at 19–22; Dkt. 20 at 9. HISD, in its motion to dismiss, argues that this portion of the claim should be barred by FCA's public disclosure doctrine. Dkt. 19 at 22. Relators argue that this allegation is just another example of a scheme they initially disclosed in their original complaint. Dkt. 20 at 9.

Finally, Relators allege that HISD billed Medicaid for services to Garret G., Blake B., and other students without parental consent. Dkt. 12 at 2. Relators contend that HISD's failure to seek parental consent removed one "check" to prevent HISD from filing fraudulent claims under the SHARS program. *Id.*; Dkt. 20 at 6.

Relators claim HISD's standard practice is to tailor special education programs to maximize Medicaid billing for medically unnecessary or unprovided services. Dkt. 12 at 7.

HISD argues in its motion to dismiss the first amended complaint that failing to receive parental consent is not a material falsification under the FCA, that the first amended complaint is not pled with the specificity required under Federal Rule of Civil Procedure 9(b), and that the amendments Relators added to the first amended complaint are barred as a public disclosure. Dkt. 19.

## II. LEGAL STANDARDS

### A. Rule 12(b)(6) Standard

A court may dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion to dismiss, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 816 (5th Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937 (2009). "Factual allegations must be enough to raise a right to relief above the speculative level...on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555. As part of the *Twombly-Iqbal* analysis, the court proceeds in two steps. First, the court separates legal conclusions from well-pled facts. *Iqbal*, 556 U.S. at 678–79. Second, the court reviews the well-pled factual allegations, assumes they are true, and then determines whether they "plausibly give rise to an entitlement of relief." *Id.* at 679.

### B. Rule 9(b) Standard

In addition to meeting the plausibility standard, under Federal Rule of Civil Procedure 9(b), if a party is alleging fraud or mistake, the pleading must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009) (noting that Rule 9(b) does not "supplant" Rule 8(a)). The Fifth Circuit observed: "In cases of fraud, Rule 9(b) has long played that screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later. We apply Rule 9(b) to fraud complaints with 'bite' and 'without apology.' " *Id.* at 185 (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997)). However, this particularity requirement "does not 'reflect a subscription to fact pleading.' " *Id.* Instead, pleadings alleging fraud must contain "simple, concise, and direct allegations of the circumstances constituting the fraud, which...must make relief plausible, not merely conceivable, when taken as true." *Id.* (internal quotations omitted) (referring to the standard enunciated in *Twombly*).

***3** The Fifth Circuit strictly interprets Rule 9(b), "requiring a plaintiff pleading fraud to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 339 (5th Cir. 2008) (quoting *Herrmann Holdings Ltd. v. Lucent Techs. Inc.*, 302 F.3d 552, 564–65 (5th Cir. 2002)). Thus, Rule 9(b) generally requires the complaint to "set forth 'the who, what, when, where, and how' of the events at issue." *U.S. ex rel. Gage v. Davis S.R. Aviation, L.L.C.*,

623 Fed.Appx. 622, 625 (5th Cir. 2015), *cert. denied*, 136 S. Ct. 984 (2016) (quoting *U.S. ex rel. Steury v. Cardinal Health, Inc.,* 625 F.3d 262, 266 (5th Cir. 2010)). However, "Rule 9(b)'s ultimate meaning is context-specific." *Grubbs*, 565 F.3d at 185. Thus, "[d]epending on the claim, a plaintiff may sufficiently 'state with particularity the circumstances constituting fraud or mistake' without including all the details of any single court-articulated standard—it depends on the elements of the claim at hand." *Id.* at 188 (internal quotation omitted).

**III. Analysis**

HISD moves to dismiss the first amended complaint because the lack of a parental consent for the Medicaid bills is not material to a false claim and because Relators failed to plead fraud with the required particularity under Federal Rule of Civil Procedure 9(b). Dkt. 19 at 6–7. The analysis will first address the materiality of parental consent and then determine if the Relators sufficiently pled their fraud claim under Rule 9(b).

**A. Materiality under the FCA**

Any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable under the FCA. 31 U.S.C. § 3729(a)(1)(A)–(B). To state a claim under the FCA, a plaintiff must allege: (1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government. *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467 (5th Cir. 2009).

In its motion to dismiss, HISD argues the false "statement" alleged by Relators is HISD's submission of SHARS claims for services performed without the requisite parental consent, which is not material to the fraud. Dkt. 19 at 10–11. In their response, Relators clarify their position on HISD's failure to procure parental consent noting that "this failure does not itself constitute the false claim that gives rise to the complaint." Dkt. 20 at 6. Rather, Relators argue that failing to procure parental consent removes a "potential check against fraudulent billing activity." *Id.* Relators clarify that their FCA claim is based on the allegation that "HISD made false statements regarding the services it provided or failed to provide special education students its tutelage and the necessity of those services" Dkt. 20 at 5. Therefore, the court will consider Relators' allegation that HISD fraudulently sought reimbursement from Medicaid for medical unnecessary services as the basis for their FCA action, and consider the alleged failure to acquire parental consent as an act that supports that allegation. The allegation that HISD fraudulently sought reimbursements for medically unnecessary services is material to the claim, so HISD's motion to dismiss on this ground is DENIED.

**B. Rule 9(b)**

The first amended complaint alleges that HISD billed Medicaid for medically unnecessary services or services not rendered at all. Dkt 12. HISD argues that the first amended complaint "failed entirely to plead the 'who' and 'when' of the fraud, and does not sufficiently plead the 'what' or 'how' to satisfy the requirements of Federal Rule of Civil Procedure 9(b)." Dkt. 19 at 10.

***4** First, in addressing the "what" and "how" of a fraud, the Relator must plead "what was false about the claims or how they were false." *U.S. ex rel. Gage v. Davis S.R. Aviation*, L.L.C., 623 Fed.Appx. 622, 625 (5th Cir. 2015), *cert. denied*, 136 S. Ct. 984 (2016). "[P]laintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted...[I]f it cannot allege the details of an actually submitted false claim, it may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (further stating the required elements of a claim are "context-specific"). "While allegations may be based upon information and belief, 'the complaint must set forth the factual basis for such belief.' " *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 329 (5th Cir. 2003) (quoting a *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)). The Fifth Circuit warns that "this exception 'must not be mistaken for license to base claims of fraud on speculation and conclusory allegations.' " *U.S. ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 385 (5th Cir. 2003) (quoting *ABC Arbitrage v. Tchuruk*, 291 F.3d 336, 350 n.67 (5th Cir. 2002)).

The facts offered by Relators to form the basis of their beliefs that establish the "what" and "how" of the fraud are, in summary, that Blake B. was kept in a Behavioral Support

Classroom without demonstrating violent tendencies, that Garrett G. was denied a free and appropriate public education, and that unspecified medically unnecessary services were provided to the two students and billed without parental consent. Dkts. 12 at 4–6, 20 at 8–9. Additionally, the Relators provide information already reported in the media that special education teachers elsewhere in the school district billed for medical services that were not provided. Dkt. 12 at 7. Relators explain in their response that this additional example was an "elucidation" provided for the purpose of "confirming the existence and character of the fraudulent scheme outlined in their Original Complaint." Dkt. 20 at 10.

As part of the first amended complaint, Relators allege the basis for their belief that HISD was engaged in fraudulent activity is that services provided to Blake B. and Garrett G. were medically unnecessary. Dkt. 12 at 5–6. HISD argues that Relators' failure to plead "what specific services were allegedly billed," means the first amended complaint is based on a conclusory allegation rather than a factual basis for their belief. Dkt. 19 at 17. In a comparable *qui tam* case regarding an alleged aircraft parts fraud, the relators described the parts as "non-conforming" and "unapproved," and the court dismissed these as conclusory terms lacking the necessary details in how the parts failed to comply. *See U.S. ex rel. Gage,* 623 Fed.Appx. at 627. Similarly, Relators here claim that services provided to special education students were "medically unnecessary" without specifying why the services are medically unnecessary or even providing an example of a service that was provided. Therefore, in this context, the court finds that "medically unnecessary" is a conclusory statement rather than a factual basis for the "what" and "how" of the 9(b) pleading.

Relators also argue that HISD's failure to procure parental consent provides a factual basis for their belief. Dkt 20 at 8. Relators explain that "[h]aving failed to obtain parental consent... HISD could more easily submit bills for unnecessary services or services not provided at all." *Id.* HISD replies that "it is pure speculation...[that this is] somehow evidence that HISD knowingly provided and billed for medically unnecessary services and/or billed for services not provided." Dkt 21 at 5. The court concludes that the failure to comply with parental consent requirements, the poor educational outcomes of Blake B. and Garrett G., and only the supporting conclusory statements are an insufficient factual basis to allow the court to make a reasonable inference to establish the "how" and "what" of the alleged fraud in this context.

***5** In addressing the "when" of a fraud, allegations must be more specific than a course of years. *See, e.g., Gage,* 623 Fed.Appx. at 627 (5th Cir. 2015) (concluding that "[Relator] Gage alleges only that defendants submitted nearly $4 million of false invoices to the government between 2009 and 2011. This range is not specific enough to comply with Rule 9(b)"); *United States ex rel. Hebert v. Dizney*, 295 Fed.Appx. 717, 722–23 (5th Cir. 2008) (allegations that defendants routinely submitted bills over the course of seven years were not sufficiently specific under Rule 9(b)) Here, Relators allege the fraud occurred over a course of years spanning from at least 2005 to 2013. Dkts. 12 at 1, 20 at 9 ("Relators allege that this fraudulent activity occurred throughout their tenure at HISD.").

Relators respond to this defect by claiming they are alleging a broad and far-reaching scheme, so that they can base their claim on specific examples of false claims pursuant to that scheme. Dkt. 20 at 8. Relators support this argument by citing to *U.S. ex rel. Rigsby v. State Farm Fire & Casualty Co.*, 794 F.3d 457, 467 n.6 (5th Cir. 2015) ("[a]dditionally, at least one other circuit permits discovery on 'the entire fraudulent scheme' where a relator 'pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme.' " (citing to *U.S. ex rel. Bledsoe v. Cmty. Health Sys. Inc.*, 501 F.3d 493, 510 (6th Cir. 2007))). However, even relying on the specific examples of Garrett G. and Blake B., Relators do not allege "when" the false claim occurred with regard to these students with any particularity other than the course of years each student was enrolled in HISD. Therefore, the court concludes that the first amended complaint does not contain the necessary details to establish the "when" required by Rule 9(b).

In addressing the "who" of the fraudulent scheme, "the identity of the person making the misrepresentation must be stated in the complaint alleging violation of the FCA in order to satisfy Rule 9(b)." *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 329 (5th Cir. 2003). The Relators did not offer the identity of any individual person making a misrepresentation or having knowledge of HISD's alleged misrepresentations. Dkt. 20 at 7. HISD argues that it should not be held liable for the "collective knowledge" of multiple individuals, without alleging a specific individual who submitted a false claim. Dkt. 19 at 12 (citing to *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-CV-3396, 2015 WL 5178074, at *29 (S.D. Tex. Sept. 3, 2015)). HISD also argues that by not identifying

any specific individuals, Relators fail to allege the requisite scienter necessary to state a claim under the FCA. Dkt. 19 at 11–12. Relators counter that it is acceptable to allege "fraud on the part of a corporate entity without alleging the specific employee responsible for that fraud." Dkt. 20 at 7 (citing to *U.S. ex rel. Bledsoe v. Comm. Health Sys., Inc.*, 501 F.3d 493, 506 (6th Cir. 2007)).

It is acceptable to plead schemes generally, as long as specific or representative examples of entities involved in the scheme are also offered. *See, e.g., Rigsby*, 794 F.3d at 467 n.6;*U.S. ex rel. Bennett v. Boston Sci. Corp.*, No. CIV.A. H-07-2467, 2011 WL 1231577, at *16 (S.D. Tex. Mar. 31, 2011) (internal citations omitted) (declining to relax a Rule 9(b) pleading standard because "the relator in the present case has not, however, alleged a representative sample or even an instance of submission...[n]or has the relator alleged that a specific physician or hospital submitted a false claim."). Ultimately, Relators fail to provide even a representative example of an individual involved in the fraudulent scheme as part of a specific or representative example, the court concludes that the first amended complaint does not contain the "who" required by 9(b).

***6** In summary, Relators fail to adequately address the how, what, when, or who of the alleged fraudulent scheme with at least enough details to allow an inference that fraud occurred. Relators failed to provide a sufficient factual basis of their allegations. Even considering the allegations that were provided in the first amended complaint in a "context specific" light, not enough particularity was alleged to allow the court to make a reasonable inference that a fraud occurred. Therefore, the court concludes that Relators have not met the pleading standards of Rule 9(b), and HISD's motion to dismiss is GRANTED.

**C. Relaxed Pleading Standard Under Rule 9(b)**

Relators argue in their response that they are entitled to a relaxed application of Rule (9)(b) in lieu of the missing particulars of the alleged fraudulent scheme because (1) the information is only available to HISD, and (2) they were still able to allege specific examples of an overarching fraudulent scheme. Dkt. 20 at 7. The pleading requirements of Rule 9(b) may be relaxed when facts relating to fraud are "peculiarly within the perpetrator's knowledge." *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 330 (5th Cir. 2003) (quoting *U.S. ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 307 (5th Cir. 1999), *abrogated on other grounds by U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 129 S. Ct. 2230 (2009)). In a *qui tam* suit, the Relators must allege that they do not have access to the particular facts relating to the fraud, or the court will not relax the requirements of Rule 9(b). *Doe*, 343 F.3d at 330 (5th Cir. 2003).

First, the Relators argue for relaxed requirements under Rule 9(b) because "information concerning the particulars of HISD's fraudulent billing activity lies entirely in the possession of HISD rather than in the possession of Relators." Dkt. 20 at 7. However, Relators are not relieved of the Rule 9(b) requirements to plead facts "where the documents containing the requisite information are in the possession of, and presumably available from, other sources." *United States ex rel. Rafizadeh v. Cont'l Common, Inc.,* 553 F.3d 869, 873 n.6 (5th Cir. 2008) (citing Doe, 343 F.3d at 330); *see also Russell*, 193 F.3d at 308 (5th Cir. 1999) (declining to relax the Rule 9(b) standard where a government entity possessed documents containing requisite information); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704 (ERK), 2009 WL 1456582, at *8 (E.D.N.Y. May 22, 2009) ("The rationale for reducing the pleading burden when information is in the defendant's possession appears to spring from the fact that an adverse party would not willingly divulge incriminating information. Where the information needed to fill out the complaint is in the hands of third parties, rather than defendants, this rationale for reducing the pleading burden does not apply."). For example, the Fifth Circuit held, in a suit against a corporate defendant, that if the government, as a third party, also had knowledge of the needed information to form the complaint, it was not particularly in the hands of the defendants.*Gage*, 623 Fed.Appx. at 627 (holding that the details of a classified contract are "not peculiarly within [Defendant] Northrop's knowledge because the USAF, as Northrop's counterparty, presumably also has knowledge of the contract"); *see also Bennett,* 2011 WL 1231577, at *16 (holding a relaxed pleading standard is not necessary because even though "[t]he defendants note that it does not have billing or reimbursement information; doctors, hospitals, and government agencies do").

Here, at least some of the information to provide a factual basis for HISD's alleged fraud should be available from a third party, such as Medicaid itself. Also, as HISD points out in its reply, Relators are legally entitled to participate in HISD Individual Education Plan meetings and receive copies of their children's educational records. Dkt. 21 at 7. Relators make no allegation that HISD is refusing to cooperate or disclose this information about Blake B. or Garrett G. The court concludes that the first amended complaint is deficient

at least in regard to the details that are available to the Relators from third parties or freely available in the student's educational records.

***7** Second, Relators argue that because this is an "overarching" scheme, the specific examples provided are sufficient to establish the fraud, implying that discovery can be used to cure any defects in the pleading. Dkt. 20 at 7–8. The Fifth Circuit has observed, "[a]dditionally, at least one other circuit permits discovery on the entire fraudulent scheme where a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government September 27, 2016 pursuant to that scheme." *Rigsby*, 794 F.3d at 480 (quoting *U.S. ex rel. Bledsoe v. CmtyHealth Sys. Inc.*, 501 F.3d 493, 510 (6th Cir. 2007)). But, the Fifth Circuit also cautions: "In cases of fraud, Rule 9(b) has long played that screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." *Grubbs,* 565 F.3d at 185.[2]

However, even if the Relators were entitled to a relaxed pleading standard allowing pleading on "information and belief," the Relators must also state the factual basis for their beliefs. *Doe*, 343 F.3d at 329. For example, in *Doe* v. *Dow Chem. Co.*, Doe failed to provide any factual basis for his belief that there were "illegal discharges at the Plaquemine facility, that certain parties knew of these discharges and their illegality, and that those parties falsified reports to the government to prevent detection." *Id.* Because of these deficiencies, the court in *Doe* did not allow a relaxed pleading standard under Rule 9(b). *Id.* Like in *Doe*, even though Relators offer Garrett G. and Blake B. as specific examples, they do not provide any factual basis to support their belief that false claims were filed on the students' behalf. A complete example would include at least some further details, such as what medical service was provided, when it was provided, when and who billed the procedure, and why that service was medically unnecessary. Currently, the allegations only include the existence of these two students and their poor educational outcomes, accompanied by conclusory statements. The first amended complaint does not provide enough factual basis for the court to infer these poor educational outcomes were caused by HISD's alleged fraudulent scheme without providing the factual basis to support that conclusion. Without the specific examples, the court concludes that the allegations provided are inadequate to provide a factual basis for Relators' belief. Therefore, without examples of specific false claims pursuant to the alleged scheme, to allow an appropriately tailored discovery, it is not appropriate to open the door to discovery as a tool to remedy the defects in the first amended complaint.

Accordingly, because Relators failed to plead with specificity a single representative example, failed to provide factual basis for their allegations based on information and belief, or support these examples with information that is not particularly in the hands of the defendants, the court concludes that Relators are not entitled to relaxation of the 9(b) pleading standard. Therefore, the motion to dismiss is GRANTED because the first amended complaint did not adequately plead the alleged fraud under Rule 9(b).[3]

## IV. CONCLUSION

***8** HISD's motion to dismiss (Dkt. 19) is GRANTED and the claims are DISMISSED WITH PREJUDICE.

Signed at Houston, Texas on September 30, 2016.

### All Citations

Not Reported in Fed. Supp., 2016 WL 5661701, Med & Med GD (CCH) P 305,758

Footnotes

1 Relators' allege that Blake B's original placement in the Behavior Support Classroom occurred when "HISD personnel informed Blake B.'s parents that Blake B. required placement in a Behavior Support Classroom due to elopements out of the classroom, despite the fact that he never injured or threatened injury either to himself or others." Dkt. 12 at 5.

2 The Fifth Circuit further notes: "Discovery can be pointed and efficient, with a summary judgment following on the heels of the complaint if billing records discredit the complaint's particularized allegations. That is the balance Rule 9(b) attempts to strike. And it works best when access to discovery does not inevitably include all discovery's powers but is tailored by the district court to the case at hand. And the detail must be sufficient to allow this tailoring. Rule 9(b) should not be made to shoulder all the burden of policing abusive discovery. Its balance draws upon the vigilant hand of the district court judge." *Grubbs,* 565 F.3d 180, 190.

3 Because the court finds that Relators fail to state a claim under Rule 9(b), the court need not address HISD's argument that the allegations added to the first amended complaint are barred are under the FCA's public disclosure provision in 31 U.S.C. § 3720(e)(4)(A).

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# APPENDIX D

KeyCite Yellow Flag - Negative Treatment
On Reconsideration in Part Ruscher v. Omnicare Inc., S.D.Tex., September 5, 2014

2014 WL 2618158
United States District Court,
S.D. Texas,
Houston Division.

UNITED STATES of America ex rel. Susan RUSCHER, et al., Plaintiffs,
v.
OMNICARE, INC. et al, Defendants.

Civ. Action No. 4:08–cv–3396.
|
Signed June 12, 2014.

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State of Georgia, pro se.

State of Hawaii, pro se.

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State of Louisiana, pro se.

Commonwealth of Massachusetts, pro se.

State of Michigan, pro se.

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State of New Hampshire, pro se.

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***MEMORANDUM AND ORDER***

KEITH P. ELLISON, District Judge.

***1** Relator Susan Ruscher has brought this False Claims Act ("FCA") *qui tam* lawsuit against Omnicare, Inc., a provider of pharmaceuticals to long-term-care facilities, as well as 200 of its affiliates and its former CEO, Joel Gemunder. In short, Relator, who served for several years as Omnicare's Collections Manger, has alleged

> an ongoing nationwide fraudulent kickback scheme in which Omnicare induces and retains business from [skilled nursing facilities or 'SNFs'] that provide services to a high volume of Medicare Part D/Medicaid patients, from whom

> Omnicare derives most of its revenues, in exchange for which Omnicare forgoes its payments for pharmaceuticals dispensed to Medicare Part A patients that the SNFs owe Omnicare.

(Doc. No. 97 ¶ 1.) Relator also named eight SNFs as Defendants in her live complaint, but she has since dismissed them. (*See* Doc. No. 119.)

The magnitude of the alleged fraud is great: Relator asserts that, by late 2009, Omnicare's overdue accounts receivable exceeded $720 million, "the majority of which represented kickbacks in the form of forgiven debt." (*Id.* ¶ 2.) The scheme, according to Relator, was also long-lasting: she alleges that it began as early as 1998 and continues to this day. The substance of her allegations fills a 200–page, 700–paragraph Third Amended Complaint ("TAC"). Now before the Court are two Motions to Dismiss: one on behalf of Omnicare and its affiliates (Doc. No. 120), and another on behalf of Defendant Gemunder (Doc. No. 126). The Court has reviewed extensive briefing submitted by the parties and the applicable law. For the reasons set forth below, Omnicare's Motion is **GRANTED IN PART AND DENIED IN PART.** Defendant Gemunder's Motion is **GRANTED.**[1]

## I. BACKGROUND

### A. Statutory and Procedural Background

*1. Statutory Scheme*

"[A]dopted in 1863 and signed into law by President Abraham Lincoln in order to combat rampant fraud in Civil War defense contracts," S.Rep. No. 99–345, at 8 (1986), the False Claims Act, 31 U.S.C. §§ 3729–3733, aims to ferret out, and impose liability for, "false or fraudulent claims for payment to the United States," *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson,* 559 U.S. 280, 283, 130 S.Ct. 1396, 176 L.Ed.2d 225 (2010). Among other things, the Act imposes civil liability upon "any person" who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(A), (B), & (G).[2] The Act also expressly bars conspiracies to violate its other provisions. *Id.* § 3729(C).

***2** Perhaps the Act's most unique feature is that it is one "of a handful of extant laws creating a form of civil action known as *qui tam.*" *Vermont Agency of Natural Res. v. United States ex rel. Stevens,* 529 U.S. 765, 768, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000). "[T]he Government itself may bring a civil action against the alleged false claimant" or "a private person (the relator) may bring a *qui tam* civil action 'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.' " *Id.* at 769 (quoting 31 U.S.C. § 3730(b)(1)). "As reward for doing so, the relators share in the government's winnings, receiving a bounty of up to thirty percent of the government's proceeds 'depending upon the extent to which the person substantially contributed to the prosecution of the action.' " *United States ex rel. Babalola v. Sharma,* 746 F.3d 157, 164 (5th Cir.2014) (Dennis, J., concurring) (quoting 31 U.S.C. § 3730(d)). All told, FCA *qui tam* suits yield annual recoveries of roughly $3 billion. *See* Civil Div., U.S. Dep't of Justice, *Fraud Statistics–Overview October 1, 1987–September 30, 2013* (Dec. 23, 2013), http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

When a False Claims Act case is initiated by a private relator, he or she must file suit under seal, 31 U.S.C. § 3730(b)(2), and "the United States is given 60 days to review the claim and decide whether it will 'elect to intervene and proceed with the action.' " *United States ex rel. Eisenstein v. City of New York, New York,* 556 U.S. 928, 932, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009) (quoting 31 U.S.C. § 3730(b)(2)). For good cause, the United States may extend that sixty-day period. 31 U.S.C. § 3730(b)(3). Where the United States does not elect to intervene, "the relator retains 'the right to conduct the action.' " *Eisenstein,* 566 U.S. at 932 (quoting 31 U.S.C. § 3730(c) (3)). The Government may still elect to intervene at a later date. 31 U.S.C. § 3730(c)(3).

*2. Procedural Background*

Relator Susan Ruscher filed her original complaint in this action in November 2008 and filed her First Amended Complaint a month later. (Doc. Nos.1, 5.) Relator filed a Second Amended Complaint in September 2009. (Doc. No. 13.) After a two-year investigation, the Government notified the Court in December 2012 that it would not intervene at that time. (Doc. No. 45.) The Court permitted Relator to file the TAC in August 2013, but ruled that she could not rely on documents subpoenaed from Omnicare by the

Government. (*See* Minute Entry, Aug. 29, 2013.) The now-pending Motions to Dismiss were filed in November 2013. (Doc. Nos.120, 126.)

**B. Factual Background**[3]

Omnicare is the nation's leader in providing pharmaceutical services to SNFs. (Doc. No. 97 ¶ 277.) Among the goods and services it provides are pharmaceuticals, specialty unit-dose packaging, delivery, pharmacist consulting, infusion and respiratory therapy, and medical supplies.[4] (*Id.*) Roughly eighty percent of the SNF patients that Omnicare serves are covered by both Medicaid and Medicare. (*Id.* ¶ 278.) Prior to 2006, Medicaid covered patients' drugs; since, Medicare Part D has done so. (*Id.*) The balance of the SNF patients that Omnicare serves are covered by Medicare Part A, rendering the institutions at which they reside eligible for reimbursement for limited inpatient stays. (*Id.* ¶ 278.)

***3** The billing and reimbursement process utilized by Omnicare varied according to whether services were provided to patients covered by Medicare Part A or Medicaid/ Medicare Part D. With respect to the patients using the Medicare Part A SNF benefit, the facilities bill Medicare on "a prospective, monthly capitated basis for all services," including pharmaceutical drugs. (*Id.* ¶ 279.) The SNFs then purchase the pharmaceuticals and other services from Omnicare, which bills the SNFs after-the-fact. (*Id.*)

Until 2005, Omnicare contracted with state Medicaid programs to provide pharmaceuticals and related services to SNF residents who were dually eligible for Medicare and Medicaid. (*Id.* ¶ 280.) Omnicare submitted reimbursement claims directly to the states for the drugs and services it provided. (*Id.*) Once Medicare Part D was created in 2006, Omnicare began to contract with Part D plan sponsors, known as PDPs, to provide pharmaceuticals and related services to dually eligible SNF residents. (*Id.* ¶ 281.) Omnicare bills the PDPs directly. (*Id.*)

In theory, the Medicare Part A prospective payments would be used by the SNFs to pay Omnicare for services provided to Part A-eligible individuals. (*Id.* ¶ 282.) According to Relator, that is not in fact what occurred. Rather, certain of Omnicare's biggest SNF clients—known within the corporation as National Accounts, Regional Holds, and P–Holds—were not required to pay Omnicare what they owed. (*Id.*) In exchange for that debt forgiveness, Omnicare came to expect those SNFs to select Omnicare as their pharmacy of choice, both for existing and new facilities, one to which they would steer all of their residents.[5] (*Id.* ¶¶ 283, 291.)

As a result, the SNFs whose debts were forgiven began to accrue substantial past-due balances, sometimes in excess of $1 million. (*Id.* ¶ 288.) Nevertheless, Omnicare's Collections Department was prohibited from contacting National Accounts. (*Id.* ¶ 287.) Instead, the National Accounts were serviced by Key Account Managers ("KAMs"), who reported to the Senior Vice President of Marketing and Executive Vice President of Operations. (*Id.* ¶ 290.) If Ruscher or anyone on her staff ever tried to contact a National Account, they would be reprimanded by the relevant KAM. (*Id.* ¶ 290.) To avoid suspicion, Omnicare's National Facility Credit and Collections Manager instructed collections department employees to note in the customer's file that the collections department had made a "reasonable attempt" to collect the past-due balance, though they never actually did so. (*Id.* ¶ 293.) The futility of its efforts earned the department the moniker, "Department of Reasonable Attempts." (*Id.* ¶ 293.) Likewise, Omnicare does not sue over such debts[6] and accepts nominal payments purely for appearance's sake. (*Id.* ¶ 288.) Ultimately, Omnicare would only write off National Account debts in the event that they became "inescapably unenforceable," such as when a customer filed for bankruptcy. (*Id.* ¶ 289.)

***4** Indeed, the SNFs designated "National Accounts" had it particularly good. Not only would their debts not be collected, the National Accounts would also receive "such perks as free pharmaceuticals and expedited refunds in order to keep existing business or regain lost business." (*Id.* ¶ 291.) Even where a National Account's debt reached into the six-or seven-figures, Omnicare did not terminate or suspend its services, fearing that if it did, it would lose the revenue it derived from serving that customer's Medicaid/Medicare Part D patients. (*Id.* ¶ 292.) By way of example, Relator notes that, by January 2008, Almaden Care, owned by Family Senior Care, owed more the $468,000, but instead of requesting that Almaden Care pay down its debt, Omnicare allowed over the next several months the past-due balance to swell to greater than $500,000. (*Id.* ¶ 292.)

As another example, Grant Park, a facility run by Shoreline HealthCare Management, and one of Omnicare's National Accounts, owed more than $1.1 million dollars by June 2008, but the KAM in charge of the facility argued against trying to collect, in light of Omnicare's ongoing attempts to acquire the

business of related facilities. (*Id.* ¶ 295.) By September 2008, Grant Park's debt had grown to $1.2 million. (*Id.* ¶ 295.)

The effect of Defendants' scheme was that the SNFs would receive "free Part A drugs in exchange for allowing Omnicare to keep and expand the number of facilities to which it provides drugs and services." (*Id.* ¶ 283.) Given the relative sizes of Omnicare's Medicare Part A business and its Medicare Part D business—Medicaid business prior to 2006—it made good business sense for Omnicare to forgive the former to grow the latter. (*Id.* ¶ 291.) The problem, at least according to Relator, was that doing so was illegal.

## II. LEGAL STANDARD

### A. Motion to Dismiss for Failure to State a Claim

A court may dismiss a complaint for a "failure to state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b)(6). "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to relief above the speculative level.' " *Cuvillier v. Taylor,* 503 F.3d 397, 401 (5th Cir.2007) (citing *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). That is, a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Twombly,* 550 U.S. at 570). A claim has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly,* 550 U.S. at 556). The plausibility standard "is not akin to a 'probability requirement,' " though it does require more than simply a "sheer possibility" that a defendant has acted unlawfully. *Id.* Thus, a pleading need not contain detailed factual allegations, but must set forth more than "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly,* 550 U.S. at 555 (citation omitted).

***5** Ultimately, the question for the court to decide is whether the complaint states a valid claim when viewed in the light most favorable to the plaintiff. The court must accept well-pleaded facts as true, but legal conclusions are not entitled to the same assumption of truth. *Iqbal,* 556 U.S. at 678–79 (citation omitted). The court should not " 'strain to find inferences favorable to the plaintiffs' " or "accept 'conclusory allegations, unwarranted deductions, or legal conclusions.' " *R2 Invs. LDC v. Phillips,* 401 F.3d 638, 642 (5th Cir.2005) (quoting *Southland Sec. Corp. v. Inspire Ins. Solutions, Inc.,* 365 F.3d 353, 361 (5th Cir.2004)). A court may consider the contents of the pleadings, including attachments thereto, as well as documents attached to the motion, if they are referenced in the plaintiff's complaint and are central to the claims. *Collins v. Morgan Stanley Dean Witter,* 224 F.3d 496, 498–99 (5th Cir.2000). Importantly, the court should not evaluate the merits of the allegation, but must satisfy itself only that the plaintiff has adequately pled a legally cognizable claim. *United States ex rel. Riley v. St. Luke's Episcopal Hosp.,* 355 F.3d 370, 376 (5th Cir.2004).

### B. Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires that a party "alleging fraud or mistake ... state with particularity the circumstances constituting fraud or mistake." Rule 9(b)'s particularity requirement "has long played [a] screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." *United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 185 (5th Cir.2009). Complaints alleging a violation of the False Claims Act come within the auspices of Rule 9(b). *Id.*

The traditional understanding of the rule is that, "[t]o plead fraud with particularity a plaintiff must include the 'time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby.' " *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.,* 193 F.3d 304, 308 (5th Cir.1999) (quoting *Williams v. WMX Tech., Inc.,* 112 F.3d 175, 177 (5th Cir.1997)), *abrogated on other grounds by United States ex rel. Eisenstein v. City of New York, New York,* 556 U.S. 928, 129 S.Ct. 2230, 173 L.Ed.2d 1255 (2009). But the Fifth Circuit has held that "the 'time, place, contents, and identity' standard is not a straitjacket for Rule 9(b)," and that imposing such requirements is more sensible in the context of common law and securities fraud claims, which require showing reliance and damages. *Grubbs,* 565 F.3d at 189–90. Because the False Claims Act demands a different ultimate showing, the court of appeals has fashioned "a workable construction of Rule 9(b)," one designed to "effectuate[ ]" the Rule's purpose "without stymieing legitimate efforts to expose fraud." *Id.* at 190. Thus, "to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong

inference that claims were actually submitted." *Id.* As for the False Claims Act's *mens rea* requirement, that "may be alleged generally." Fed.R.Civ.P. 9(b).

***6** In the main, Relator and Defendants agree that *Grubbs* sets forth the relevant interpretation of Rule 9(b). (*Compare* Doc. No. 120 at 33–34 *with* Doc. No. 137 at 28.)

## III. OMNICARE'S MOTION TO DISMISS

### A. 31 U.S.C. § 3729(a)(1) (former)/31 U.S.C. § 3729(a)(1)(A) (current)

As introduced above, the False Claims Act subjects to civil liability "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A).[7] The Fifth Circuit has "summarized that to state a claim under the FCA, a plaintiff must allege: (1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government." *United States ex rel. Steury v. Cardinal Health, Inc.,* 625 F.3d 262, 267 (5th Cir.2010) (citing *United States ex rel. Longhi v. United States,* 575 F.3d 458, 467 (5th Cir.2009)).

The most straightforward FCA claims arise when a claimant requests compensation for services which he has not performed, or overcharges for those that he has completed. *See United States ex rel. Parikh v. Citizens Med. Ctr.,* 977 F.Supp.2d 654, 662 (S.D.Tex.2013) (citing, e.g., *United States ex rel. El–Amin v. George Wash. Univ.,* 522 F.Supp.2d 135, 141 & n. 5 (D.D.C.2007); *United States ex rel. Hafter v. Spectrum Emergency Care, Inc.,* 190 F.3d 1156, 1164 (10th Cir.1999)). But there also exists another variety of FCA claim. "Under some circumstances, accurate claims submitted for services actually rendered may still be considered fraudulent and give rise to FCA liability if the services were rendered in violation of other laws." *Id.* (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 902 (5th Cir.1997)). The Fifth Circuit has explained that, "where the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation." *Thompson,* 125 F.3d at 902. In such cases, "a defendant's violation of a law on which the government conditions payment may serve as a 'predicate' violation that invokes FCA liability." *Parikh,* 977 F.Supp.2d at 662.

The criminal Anti–Kickback Statute ("AKS"), 42 U.S.C. § 1320a–7b(b), is one such law. The AKS makes illegal "knowingly and willfully solicit[ing] or receiv [ing]" or "offer[ing] or pay[ing]"

> any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind ... (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

***7** *Id.* § 1320a–7b(b)(1)(A)-(B). In other words, "[t]he Medicare anti-kickback statute prohibits (1) the solicitation or receipt of remuneration in return for referrals of Medicare patients, and (2) the offer or payment of remuneration to induce such referrals." Thompson, 125 F.3d at 901. When it forms the basis of an FCA claim, an AKS violation must be pleaded with particularity. *See United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.,* 519 F. App'x 890, 894 (5th Cir.2013) (per curiam).

It is now the case, thanks to one of the lesser-known provisions of the Patient Protection and Affordable Care Act ("PPACA"), Pub.L. No. 111–148, § 6402(f), 124 Stat. 119, 759 (2010) that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of" the FCA, regardless of whether other criteria, like certification, are satisfied. 42 U.S.C. § 1320a–7b(g). The parties here—or, more specifically, the United States as interested non-party and Defendants—dispute whether that was true when the events underlying this case took place. The United States urges that the PPACA amendment to the AKS merely codified pre-existing law; Defendants contend that, prior to the amendment, an AKS violation could only serve as a predicate to an FCA claim in the event that the claimant had certified compliance with the AKS. For reasons that will become clear below, the Court need not ultimately resolve that dispute.

Thus, in light of the applicable law and the arguments made by Defendants in support of dismissal, the Court answers the following questions in turn:

(1) whether Relator has alleged a violation of the AKS;

(2) whether Relator has sufficiently alleged certification of compliance, or, if not, whether she was not in fact required to do so; and

(3) whether Relator alleged the details of an actually submitted false claim, or, if not, whether she has alleged particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

*1. Whether Relator Has Alleged an AKS Violation*

Defendants make several AKS-specific arguments as to why Relator's Complaint should be dismissed for failure to state a claim. First, they argue that Relator "has not alleged that Omnicare actually wrote off, or cleared the amounts due, never intended to collect the debt, or that any delay in collection was for the purpose of inducing a specific customer to give any Omnicare pharmacy Medicare Part D or Medicaid business." (Doc. No. 120 at 24.) Further, Defendants assert that, for three reasons, Relator has failed to comply with Rule 9(b) and plead the AKS violation(s) with particularity. Defendants assert that Relator "fails to identify any referrals for business that Omnicare unlawfully obtained and billed to federal or state health programs as a result of alleged kickbacks," "does not sufficiently identify who allegedly violated the AKS because she does not adequately distinguish between the 211 named defendants that Relator has collectively defined as Omnicare," and "does not sufficiently identify when Omnicare's alleged scheme to violate the AKS took place." (*Id.* at 35–36.)

a. *Challenges Sounding in Rule 12(b) (6 )*

***8** Defendants have failed to convince the Court that forgiven debt cannot be considered remuneration. Courts have "interpreted the meaning of 'remuneration' broadly as 'anything of value in any form whatsoever,' reasoning that '[t]he Anti–Kickback Statute uses the term any remuneration, which suggests an expansive reading of the form of any kickback directly or indirectly, as opposed to a narrow reading.' " *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.,* No. 2:08–CV–00114, 2012 WL 628515, at *5 (S.D.Ohio Feb.27, 2012) (quoting *United States ex. rel. Fry v. The Health Alliance of Greater Cincinnati,* No. 1:03–CV–001672008, 2008 WL 5282139, at *7 (S.D.Ohio Dec.18, 2008)). In *Fry,* the court relied on the *Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti–Kickback Provisions,* 56 Fed.Reg. 35952, 35958 (July 29, 1991), which it read to be "unambiguous in offering a broad definition of the term 'remuneration' as 'anything of value in any form whatsoever.' " *Fry,* 2008 WL 5282139, at *7. Those regulations explain that "Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever" and that "[t]he statute's language makes clear that illegal payments are prohibited beyond merely 'bribes,' 'kickbacks,' and 'rebates,' which were the three terms used in the original 1972 statute." 56 Fed.Reg. at 35958. Likewise, the regulations note that "[t]he statute's legislative history ... makes clear that the fundamental analysis required of a trier of fact is 'to recognize that the substance rather than simply the form of a transaction should be controlling.' " *Id.* (quoting 123 Cong. Rec. 30,280 (1977), Statement of Chairman of the House Committee on Ways and Means and principal author of H.R. 3, Representative Rostenkowski; H .R. Rep. No. 393, part II, 95th Cong., lst Sess. 53; *reprinted in* (1977) U.S.Code Cong. & Ad. News 3056; S.Rep. No. 453, 95th Cong., lst Sess. 12 (1977)).

Against this backdrop, Defendants' argument that Omnicare would have had formally to write the debt off of its books in order for the forgiven balances to be considered remuneration appears dubious. Unsurprisingly, then, the courts that have recently confronted similar factual scenarios have found that forgiven accounts receivable can amount to remuneration for AKS purposes. In *United States ex rel. Fontanive v. Caris Life Scis., Inc.,* No. 3:10–cv–2237–P, slip op. at 23 (N.D. Tex. Oct 23, 2013),[8] the district court was confronted with a defendant that "declined to collect from client hospitals over a million dollars in bills" because "[i]t was afraid that issuing technical component bills would cause client hospitals to stop referring patients for Target Now services." *Id.* at *23. The court found the uncollected balances sufficient to constitute remuneration. Similarly, in *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc. .,* No. 2:08–CV–00114, 2012 WL 628515 (S.D.Ohio Feb.27, 2012), the relator alleged that "Mobilex regularly chose simply not to collect its accounts receivable from the nursing homes, effectively providing its services for free." *Id.* at *3. That court too found that relator had properly alleged an AKS violation. And, in *In re Pharm. Indus. Average Wholesale Price Litig.,* 478 F.Supp.2d 164 (D.Mass.2007), the court included "debt forgiveness" in a list of "special incentives" that, "if paid with corrupt intent, would be paradigm instances of behavior prohibited by anti-kickback legislation." *Id.* at 177.

***9** This Court agrees. Precedent dictates that the Court's inquiry should be functional and not formal, and so it has little trouble concluding that, if Omnicare did in fact, with the requisite *mens rea,* forgo payments on accounts receivable, that debt forgiveness would constitute "remuneration." It is not enough for Defendants to argue that "Relator ignores all conceivable legitimate reasons for delay in collecting, including but not limited to contract payment terms, billing errors, and billing disputes." (Doc. No. 120 at 11.) Rather, Defendants will have a chance to show any one, or all of, those things as this case proceeds and can press those arguments when it comes time for summary judgment. The Court is likewise unmoved by Defendants' assertion that "Relator's allegation that Omnicare did not sue large accounts for overdue balances is demonstrably wrong." (*Id.* at 22 (citing Doc. No. 97 ¶ 282, 302).) Though the Court agrees that the mere existence of lawsuits against certain customers is judicially noticeable, *see Ferguson v. Extraco Mortgage Co.,* 264 F. App'x 351, 352 (5th Cir.2007) (per curiam) ("A court may take judicial notice of 'a document filed in another court ... to establish the fact of such litigation and related filings,' but generally cannot take notice of the findings of fact from other proceedings because those facts are usually disputed and almost always disputable." (quoting *Taylor v. Charter Med. Corp.,* 162 F.3d 827, 830 (5th Cir.1998))), the Court does not deem those lawsuits probative without digging deeper into, for example, the amounts in controversy and the degree to which those amounts comprised the total accounts receivable that Omnicare was owed. And *those* facts are not judicially noticeable. That Omnicare sued for past-due balances may well become highly relevant down the road, but the Court is not yet prepared to alter its conclusion because of it. It is convinced that Defendants' 12(b)(6) challenge to Relator's AKS allegations is without merit.

b. *Challenges Sounding in Rule 9(b)*

*i. Legal Standard*

Adequately analyzing Defendants' Rule 9(b) challenges requires taking a closer look at how that rule applies to Anti–Kickback Statute violations that serve as False Claims Act predicates. There is no doubt that AKS violations come within Rule 9(b)'s ambit, and it is of course the general rule, that, while "[w]hat constitutes 'particularity' will necessarily differ with the facts of each case ... [a]t a minimum ... Rule 9(b) requires the who, what, when, where, and how to be laid out." *Benchmark Electronics, Inc. v. J.M. Huber Corp.,* 343 F.3d 719, 724 (internal quotation marks omitted), *opinion modified on denial of reh 'g,* 355 F.3d 356 (5th Cir.2003). It is also true, though, that in the context of FCA claims, "if [Relator's Complaint] cannot allege the details of an actually submitted false claim," it "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Grubbs,* 565 F.3d at 190. Yet, as the *Parikh* court recently noted, "though the *Grubbs* court relaxed the standard for pleading presentment of false claims ... it did not relax the pleading requirements for alleging the existence of the more crucial element—the scheme." *Parikh,* 977 F.Supp.2d at 671.

***10** The question remains, then, whether a relator must allege the "the who, what, when, where, and how" of each alleged kickback in order to allege with particularity the existence of a scheme to submit false claims that is grounded in the payment of kickbacks. The Court believes that doing so is not necessary, but a deeper dive is necessary to determine just what does satisfy Rule 9(b).

*Parikh* serves as a useful reference. There, the court explained that "[t]o plead FCA liability predicated on AKS violations, Relators need only allege the particular details of a scheme to offer kickbacks in order to induce referrals." *Parikh,* 977 F.Supp.2d. at 667. Judge Costa considered Rule 9(b) challenges to the relator's complaint as it related to six different groups of physicians that referred patients to the defendant. Where Judge Costa found "allegations that, if true, provide a strong inference of the existence of a kickback scheme," he allowed a claim to go forward. *Id.* at 670. He took a common sense approach to that inquiry, noting, for example, that with respect to one group of doctors, the inference that a kickback scheme existed "[wa]s particularly strong given that it would make little apparent economic sense for [defendant] Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals." *Id.* at 670–71.

On the other hand, where Relator had "allege[d] two specific instances in which [a group of doctors] or their assistants made referrals in exchange for improper benefits," but "d[id] not explain how these incidents f[e]ll into a larger scheme or plan to violate the FCA," the *Parikh* court found the allegations insufficient. *Id.* at 671. The allegations regarding the scheme were deficient, with respect to that particular group of doctors, because "[t]he Court [wa]s left to speculate how the hospitalists [we]re receiving improper compensation, by what means Citizens [wa]s attempting to induce them to make referrals, or how Citizens [wa]s supposed to benefit

from the referrals." *Id.* Without those details, the Court could not find Rule 9(b)'s particularity requirement satisfied.

The Court thus concludes that, to allege the particulars of a scheme to offer kickbacks, Relator must sketch how it was that Defendant provided remuneration to its clients, the form of that remuneration, how and why Defendant believed that remuneration would induce new business, and how Defendant benefited from the remuneration. In keeping with Rule 9(b), Relator must allege the timeframe in which the scheme took place and which components of the Defendant organization were involved, even if she cannot allege the exact dates on which kickbacks were provided and the names of each individual within Omnicare who authorized a kickback.

This conclusion is bolstered by another line of precedent that "ha[s] ... relaxed Rule 9(b)'s pleading standard where the alleged fraud occurred over an extended period of time and consists of numerous acts." *United States ex rel. Foster v. Bristol–Myers Squibb Co.,* 587 F.Supp.2d 805, 821 (E.D.Tex.2008); *see also United States ex rel. Davis v. Lockheed Martin Corp.,* No. 4:09–CV–645–Y, 2010 WL 4607411, at *3 (N.D.Tex. Nov.15, 2010) ("But in cases where the plaintiff is alleging that the fraud occurred over a period of years, the plaintiff is not required to allege all facts supporting every instance when the defendant engaged in fraud."); *United States ex rel. Lam v. Tenet Healthcare Corp.,* 481 F.Supp.2d 689, 697 (W.D.Tex.2007) ("These pleading requirements are relaxed where the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge or when the alleged fraud occurred over a multiyear period."); *United States ex rel. King v. Alcon Labs., Inc.,* 232 F.R.D. 568, 570 (N.D.Tex.2005) ("However, in cases where the plaintiff is alleging that the fraud occurred over a multiyear period, the plaintiff is not required to allege all facts supporting each and every instance when each defendant engaged in fraud."); *Thompson,* 20 F.Supp.2d at 1039 ("Furthermore, Relator notes, courts have consistently found that where allegations of fraudulent conduct are numerous or take place over an extended period of time, less specificity is required to satisfy the pleading requirements of Rule 9(b)."); *United States ex rel. Johnson v. Shell Oil Co.,* 183 F.R.D. 204, 206–07 (E.D.Tex.1998) (collecting cases).

***11** Still, even where courts have adhered to a relaxed Rule 9(b) standard, they have not budged from the basic rule that the complaint must include a "sufficient factual basis for [Plaintiff/Relator's] belief." *Foster,* 587 F.Supp.2d at 822. This can often take the form of a "representative sample" of the alleged wrongdoing. *United States ex rel. Bennett v. Boston Scientific Corp.,* No. CIV.A. H–07–2467, 2011 WL 1231577, at *17 (S.D.Tex. Mar.31, 2011); *see also King,* 232 F.Supp.2d at 572 (finding that, even under a relaxed pleading standard, relators failed to plead fraud with particularity because they did not identify a single person involved in the alleged fraud, did not point to specific fraudulent claims, and did not specify a single date on which fraudulent activity occurred); *Lam,* 481 F.Supp.2d at 688 (finding that even under a relaxed pleading standard, relators' complaint failed because they failed to name one physician who violated the anti-referral statute, did not specifically identify one fraudulent transaction, and alleged only that the fraudulent events occurred "at some point in the 1980s, between 1995 and 2002, and in 1999").

Thus, in view of the Court's understanding of how Rule 9(b) operates in the specific context of FCA claims predicated on AKS violations, Defendants' Rule 9(b) challenges largely fail, for the reasons set forth below.

*ii. Whether Relator Has Alleged—Or Needed To Allege—Inducement*

In what could be characterized as a challenge to the "what" and the "how" of Relator's allegations, Defendants argue that "Relator fails to allege that the forgiveness of any accounts receivable balance by any Omnicare entity caused any specific customer to give federal health care business to that Omnicare entity." (Doc. No. 120 at 21.) Looked at another way, Defendants argue that Relator needs to have alleged that forgiving accounts receivable actually induced customers to send Omnicare new business. But, as the *Parikh* court observed, "the AKS does not require actual inducement." *Parikh,* 977 F.Supp.2d at 664. Rather, "[t]he AKS's plain language thus makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results." *Id.* at 665.

Nevertheless, Defendants can point to the Fifth Circuit's decision in *Nunnally,* 519 F. App'x 890, to contend that "actual inducement is an element of the AKS violation." *Id.* at 894. The *Parikh* court considered, and rejected, that argument. The aforesaid language from *Nunnally,* the court explained, "appears at odds with both the language of the AKS and precedent applying that statute." *Parikh,* 977 F.Supp.2d at 665. The *Nunnally* quotation is at odds with the statutory language because "[t]he AKS's plain language ... makes it unlawful for a defendant to pay a kickback with the intent to induce a referral, whether or not a particular referral results,"

*id.* (citing 42 U .S.C. § 1320a–7b(b)(2)(A)), and runs counter to precedent applying that statute because that "[c]ase law ... consistently treats the AKS's inducement element as an intent requirement," *id.*

***12** The *Parikh* court noted that the "actual inducement" quotation from *Nunnally* actually "turns out to be at odds with *Nunnally* itself." *Id.* Rather, what *Nunnally* demanded that relator plead was " 'that [the defendant] knowingly paid remuneration to specific physicians in exchange for referrals'—the commonly accepted understanding of the AKS's inducement requirement." *Id.* (quoting *Nunnally,* 519 F. App'x at 894). What is more, as *Parikh* also noted, *Nunnally* is unpublished and therefore not binding. *Id.*

Thus, with respect to inducement, all that Relator must do is plead that Omnicare acted with the "intent to induce referral of federal health care program business." *United States v. Omnicare, Inc.,* No. 11–CV–8980, 2014 WL 1458443, at *9 (N.D.Ill. Apr.14, 2014) (citing *Klaczak v. Consol. Med. Transp.,* 458 F.Supp.2d 622, 675 (N.D.Ill.2006); *Osheroff,* 2012 WL 2871264, at *8). The Court is satisfied that Relator has done so. For instance, the Complaint alleges that "[i]n exchange [for debt forgiveness], Omnicare chiefly expects, in addition to other opportunities, these [SNFs] to choose Omnicare as the pharmacy for their residents." (Doc. No. 97 ¶ 283.) More specifically, Relator has alleged that "Harborside Healthcare Corporation ... received favorable treatment from Omnicare in an effort to retain its business" and that "Omnicare sought to gain the business of Harborside's newly acquired facilities." (*Id.* ¶ 294.) Similarly, Relator asserts that an Omnicare official argued against collecting from Grant Park, a facility affiliated with Shoreline HealthCare Management, "because Omnicare was attempting to acquire the business of related facilities." (*Id.* ¶ 295.) In the same vein, Relator alleged that "Omnicare's concern in protecting P–Holds and Regional Holds from Collections is with soliciting and retaining the lucrative Medicaid and Medicare Part D business." (*Id.* ¶ 298 (citing TAC Ex. 1).) Also probative, if a bit less so, is Relator's allegation that she sought to advise her superiors that Five Star Quality Care should be forced to pay its outstanding balance before being offered a new contract, but that she was told not to discuss Five Star's past due balance and informed that Omnicare was in the process of negotiating to buy Five Star's pharmacy business, a transaction that was indeed successfully consummated down the road.[9] (*Id.* ¶¶ 311–12.) Finally, Relator contends that she "once became so frustrated about the number of accounts accruing increasing debt ... that she confronted her supervisor, Richard Richow. He reminded her that Omnicare makes a great deal of money from the Medicaid (and, after January 1, 2006, Medicare Part D) beneficiaries at those facilities and said that Omnicare did not want to risk losing that income."[10] (*Id.* ¶ 313.) Read together, these allegations evince intent to induce new business sufficient to survive this Motion to Dismiss.

*iii. Whether Relator Has Alleged "Who" Was Involved in Omnicare's Scheme*

***13** Defendants also challenge Relator's Complaint on the grounds that she "does not sufficiently identify who allegedly violated the AKS because she does not adequately distinguish between the 211 named defendants that Relator has collectively defined as Omnicare." (Doc. No. 120 at 35–36.) Relator counters that "[t]here is no doubt that Omnicare, Inc. perpetrated this scheme as a single business entity, sharing employees, offices, and business names with its individual pharmacies." (Doc. No. 137 at 33 (citing Doc. No. 97 ¶ 315).) Further, Relator explains that "Omnicare Inc.'s central organization ... sets policies, dictating how each SNF nationwide is categorized and treated.... Thus, while Omnicare might comprise several small entities, collectively, Omnicare, Inc. is a culpable 'who' in this fraud.' " (*Id.* (citing Doc. No. 97 ¶¶ 286, 288).)

Relator also points to CEO Joel Gemunder as part of the "who." She explains that "Gemunder took an active and aggressive part in curtailing the Credit and Collections department's ability to perform its most basic function: collect Omnicare's outstanding liability." (Doc. No. 137 at 33.) Relator alleged that National Accounts debts fell under the purview of Gemunder and his senior management team (Doc. No. 97 ¶ 288); that Gemunder (or another specifically named Omnicare executive) "demanded that [Relator] cease collections efforts immediately" whenever she contacted a National Account (*id.* ¶ 308); and that Omnicare staffers were hesitant to ever try to collect from a large account "because they [would] then face a tongue-lashing or worse from Omnicare leadership, including then CEO Joel Gemunder" (*id.* ¶ 315). Whether these allegations would be enough to overcome Gemunder's Motion to Dismiss is a different matter; but in any event, they certainly help to establish who was involved in Omnicare's kickback scheme.

Additionally, Relator notes that she "isolated the beneficiaries of Defendants' kickbacks: Omnicare's National and P–Hold account-holders." (Doc. No. 137 at 34 (citing Doc. No. 97 ¶

282).) She points to the aging spreadsheets, attached to her Complaint, that "identify[ ] each localized subsidiary as well as its preferred corporate owner by name." (Doc. No. 137 at 34.) And, she notes that she "isolated eight of Defendants' most favored SNFs and alleged specific examples of these SNFs' fraudulent conduct." (Doc. No. 137 at 34 (citing Doc. No. 97 ¶¶ 338–67).) Indeed, those paragraphs cited by Relator go into fairly significant detail about the conduct of Shoreline HealthCare Management, Five Star Quality Care, Harborside Healthcare/Sun Healthcare Group, Inc., Life Care Centers of America, Inc., Avamere Health Services, LLC, Family Senior Care, Millennium Management, LLC, and Fundamental Long Term Care Holdings, LLC/Trans Healthcare, Inc. These summaries included snapshots of total debts due at given times, a sense of how a National Accounts' debt increased over time, and illustrations of individual facilities that were particularly delinquent. (*See, e.g.,* Doc. No. 97 ¶¶ 339–42.)

***14** In their reply, Defendants contend that, despite these allegations, Relator's Complaint fails because "none of these allegations identify the individual or individuals who were involved in implementing the alleged fraudulent scheme at issue." (Doc. No. 139 at 17–18.) That contention, however, fails as a matter of fact and as a matter of law. As to the former, Relator has alleged the role that Gemunder and others on his senior management team played, and has gone into some detail as to the role played by Michael Rosenblum, Executive Director of Omnicare's New York subsidiary. (Doc. No. 97 ¶¶ 297, 313, 314, 316.) For instance, Relator alleged that

> it was Rosenblum who expressly prohibited Ruscher and her staff from collecting on accounts in Rosenblum's New York region. Rosenblum kept P–Holds on most of his accounts because he was afraid that any collection efforts would cause his customers to cease doing business with Omnicare.... Rosenblum also made unwritten settlement agreements with his customers that could not be enforced by Omnicare, presumably in an effort to appear as if he were collecting past-due amounts while appeasing his customers at the same time. The amount owed by his customers was typically astronomical ...

(*Id.* ¶ 314.)

As for the law, Defendants rely on two cases for the proposition that Relator needed to plead the specific identities of those involved in Omnicare's kickback scheme. First, in *Thompson v. LifePoint Hospitals, Inc.,* No. CIV.A. 11–01771, 2013 WL 5970640 (W.D.La. Nov.8, 2013), the relator had alleged that Defendant "violated the [AKS] ... by providing Dr. Robert Craig, a non-employee physician, housing at less than the fair market rent as an incentive to relocate to Ville Platte and refer patients under his care to Ville Platte Medical Center." *Id.* at *2. The court held that, because relator had not "describe[d] when this supposed arrangement began or ended or any details of the arrangement, *i. e* . how much rent was paid, what apartment Relator is referring to, or who was involved in setting up the arrangement," relator had "fail[ed] to meet the bar required by Rule 9(b)." *Id.* at *5. While the Court certainly understands why Defendants cite to it, *LifePoint Hospitals* is only mildly persuasive. The Complaint in *LifePoint Hospitals* appears to have been so utterly devoid of crucial details that it does not seem possible to extrapolate that, had more detailed information about "who" took part in the alleged kickback been the only thing the Complaint was missing, it still would have failed under Rule 9(b). Moreover, the Court distinguishes *LifePoint Hospitals* on the grounds that "who" can be viewed differently in the context of a pervasive, company-wide scheme, as Relator has alleged in this case, than when a single incident was alleged, as was true in *LifePoint Hospitals.* It is only natural that it will be harder to point to specific individuals when discussing a kickback scheme that (allegedly) became, in essence, a part of the corporate culture.

***15** The second case relied upon by Defendants is likewise unpersuasive. In *United States ex rel. Wismer v. Branch Banking & Trust Co.,* No. 3:12–CV–1894–B, 2013 WL 5989312 (N.D.Tex. Nov.12, 2013), the court determined that relator "ha[d] not alleged specific factual details of a fraudulent scheme," though, importantly, *not* because relator had not pleaded enough about who was involved. *Id.* at *5. As such, because relator could not avail himself of the *Grubbs* 'exception' to Rule 9(b), the Court determined that he needed to have pleaded "the who-whatwhen-where-and-how" of actually submitted false claims. *Id.* And because relator had not pleaded who submitted any false claims, the court granted defendant's motion to dismiss. Thus, all that *Wismer* stands for is that, where it is necessary to plead with particularity "who" did something, relator must actually do so. This unremarkable proposition does not move the Court.

In short, because it is the scheme that Relator must allege with particularity, not the individual kickbacks, and in light of the *somewhat* relaxed pleading standard that applies to allegations of long-running fraud, Relator has pleaded enough "who" to survive this Motion.

*iv. Whether Relator Has Alleged "When" Omnicare's Scheme Took Place*

Along the same lines, Defendants argue that Relator "does not sufficiently identify when Omnicare's alleged scheme to violate the AKS took place." (Doc. No. 120 at 36.) Defendants suggest that "Relator does not allege when anyone within Omnicare authorized the kickbacks, when the alleged scheme began, or when any account balances were forgiven." (*Id.*) Defendants also point out that "[a]ll of her allegations regarding amounts due from certain customers at certain periods of time are based on exhibits dated between January and September 2008" and argue that "[s]uch allegations do not alert Omnicare to a sufficiently precise time frame to satisfy Rule 9(b)." (*Id.*) Relator counters that she "alleged that Omnicare's scheme dates from at least 1998 to the present" and that she "provided ample information to substantiate these dates, including specific details of events occurring before, during, and after her tenure." (Doc. No. 137 at 35.)

Neither party is quite right. Relator worked at Omnicare from July 2005 until August 2008. (Doc. No. 97 ¶ 304.) She points to e-mails discussing past-due bills sent in 2006 (Doc. No. 97 Ex. 8) and she specifically cites balances due between January and September 2008, (Doc. No. 97 ¶¶ 292–95). Relator's aging spreadsheets show numerous six-or even seven-figure debts that, in January 2008, had been due for at least nine months. (Doc. No. 137 at 35 (citing TAC Ex. 48).) And in her brief, she makes a compelling case for why many of those balances accrued over some time—not less than 180 days, but in at least some cases, much longer. For example, she identifies a facility that, by January 2008, had accrued more than $1.1 million in debt older than nine months, and because that facility's average bill was less than $51,000 per month, she surmises that the outstanding debt represented at least two years of unpaid bills. (Doc. No. 137 at 35 .) Having reviewed the aging spreadsheets attached to the TAC as exhibits, the Court has no trouble inferring that the balances due accrued over extended time periods. And, as Relator points out, courts have agreed that a relator's termination does not necessarily evince that a scheme has come to an end—especially a scheme like this, where balances grow at a somewhat predictable pace—and so the Court does not feel compelled to throw out all allegations that took place after Relator's departure from Omnicare. *See United States v. Medtronic, Inc.,* No. 95–1236–MLB, 2000 WL 1478476, at *3 (D.Kan. July 13, 2000) ("[Relator] was subsequently terminated in August 1994. A reasonable temporal scope of discovery, absent other justification, is January 1990 to January 1995."); *see also Strom ex rel. United States v. Scios, Inc.,* 676 F.Supp.2d 884, 895 (N.D.Cal.2009) ("Subsequent attempts [to] shift course on their own do not absolve Defendants for earlier allegedly fraudulent activity.").

***16** The Court is therefore convinced that Relator has satisfied Rule 9(b)'s particularity requirement for allegations of kickbacks that took place between 2005 and 2008. But the leap from that three-year period to "1998 to the present" is remarkable, and ultimately unsupportable. The only references in the TAC to "1998" appear in her short renditions of why Defendants have violated state false claims acts and are entirely conclusory in nature. (*See, e.g.,* Doc. No. 97 ¶ 459 ("Omnicare and/or the SNF Defendants knowingly violated Cal. Gov't Code § 12651(a) from at least 1998 to the present ...").) In contrast, virtually every occurrence recounted in the "Factual Allegations" section of the TAC took place between 2005 and 2008. (*See, e.g., id* ¶¶ 277–289, 292, 294, 298.) The Court can see no particularized basis whatsoever for the assertion that Defendant's scheme began as early as 1998 or continued past the close of 2008. Indeed, it is hard to distinguish the instant case from *Sealed Appellant I v. Sealed Appellee I,* 156 F. App'x 630 (5th Cir.2005), in which the Fifth Circuit explained that, "the complaint alleges that on or about August 31, 2001, Appellant was fired, but does not allege how Appellant knows that Appellee submitted false billing statements after that time.... [T]he allegations of fraud outside of that time frame are based on Appellant's extrapolations and good faith belief; this is simply not sufficient under Rule 9(b)." *Id.* at 633 (citing *Columbia/HCA Healthcare,* 125 F.3d at 903). It would appear that, here too, Relator relies on nothing more than extrapolation and good faith belief, and that is not enough.

The cases that Relator cites for the proposition that "courts have often recognized that a scheme does not begin or end with the relator's employment" support limiting this case to those claims arising out of kickbacks paid between 2005 and 2008, not 1998 to the present. In *Medtronic, Inc.,* 2000 WL 1478476, the court determined that, though relator had asked for discovery covering a twenty-year period, because the "complaint allege[d] that [relator] first observed the alleged misconduct when he relocated to Wichita as a Medtronic sales representative in October 1991" and "was subsequently terminated in August 1994," "[a] reasonable temporal scope of discovery, absent other justification, is January 1990 to January 1995." *Id.* at *3. The Court takes from that decision that allegations of fraudulent conduct on a certain day can provide the particularized basis to believe fraud also occurred shortly before or shortly after, but not to extrapolate that fraud occurred whenever, and for as long as, relator might

baldly claim—at least not without "other justification." And no "other justification" has been offered here.

*Strom* is a more instructive decision. To simplify the allegations a bit, the United States alleged in *Strom* that defendant Scios "encourage[ed] a use of [a] drug that was not authorized by the FDA"—an "off-label" use. 676 F. Supp 2d. at 887. That "reckless" promotion "caused doctors to submit claims for treatment that were not reasonable and necessary, and hence were not eligible for reimbursement under Medicare." *Id.* at 890. Although the complaint acknowledged that the improper promotional activities terminated in July 2005, the court declined to dismiss allegations of false claims submitted thereafter, because "the broader allegations suggest[ed] that the only reason *any* doctor prescribed [the drug] was because of Defendants' earlier promotion." *Id.* at 894.

***17** As this Court reads it, *Strom* stands for the proposition that, where predicate acts are committed during one time period, but necessarily lead to false claims being presented outside that time period, the later-presented false claims should not be disallowed merely because relator has not alleged predicate acts occurring around the same time. *Id.* at 894–95. Applied to the facts of this case, *Strom* dictates that, even if Relator cannot adequately allege kickbacks occurring after 2008, it may well be the case that false claims arising out of kickbacks she has pleaded with particularity were not submitted to the Government until a later time. The Court cannot yet make that determination.

In view of the foregoing, the Court therefore grants the Motion to Dismiss as to claims arising out of kickbacks paid before January 1, 2005 and after December 31, 2008. The Court acknowledges that its analysis of *Strom* leads to a conclusion more about presentment than about AKS violations. Thus, put in the language of presentment, as discussed below, the Court believes that Relator has pleaded with particularity AKS violations that took place between 2005 and 2008, and that so pleading gives rise to "reliable indicia leading to a strong inference that claims were actually submitted" after 2008. *Grubbs,* 565 F.3d at 185–86; *cf. United States ex rel. King v. Solvay S.A.,* No. CIV.A. H–06–2662, 2013 WL 820498, at *4 (S.D.Tex. Mar.5, 2013) (undertaking a similar analysis of Strom but finding that "Relators did *not* provide any reliable indicia that lead to a strong inference that claims were actually submitted after [certain] dates" (emphasis added)). But because the Court can only draw an inference, it is possible that the Court may reach a different conclusion at the summary judgment stage.

*2. Whether Relator Has Alleged Certification*

As introduced above, "the general rule is that a defendant's violation of a separate law can serve as a predicate to FCA liability only when 'the government has conditioned payment of a claim upon a claimant's certification of compliance with' that law, and the claimant 'falsely certifies compliance with that statute or regulation.' " *Parikh,* 977 F.Supp.2d at 663 (quoting *Thompson,* 125 F.3d at 902); *see also LifePoint Hospitals,* 2013 WL 5970640, at *5 ("A violation of the AKS can serve as the basis for a FCA claim when the Government has conditioned payment of a claim upon the claimant's certification of compliance with the statute, and the claimant falsely certifies compliance.").

To satisfy this requirement, Relator relies upon "specific express certifications of compliance with the AKS accompanying Medicare enrollment forms and provider agreements and Medicare/Medicaid cost reports." (Doc. No. 137 at 23.) Indeed, the TAC is chock full of allegations of false certification. Relator has specifically referenced each of these documents (*see, e.g.,* Doc. No. 97 ¶¶ 245–46, 391, 394, 397, 403), and has alleged in more general terms the identities of the entities making the certification (*see, e.g., id.* ¶ 245 ("To participate in Medicare, providers such as pharmacies, Omnicare included, and pharmacists, must sign enrollment agreements."); *id.* ¶ 391 ("Each of Omnicare's skilled nursing facility customers, including the Skilled Nursing Facility Defendants, has submitted ...")). As just one example, Relator has pleaded that "Medicare and Medicaid require skilled nursing facilities, including but not limited to, the SNF Defendants named in this complaint, to submit regular, detailed cost reports accounting for their assets, transactions, and costs." (*Id.* ¶ 246.) She alleges that the form used to make cost reports contains certification language stating that "if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil, and administration action, fine and/or imprisonment may result." (*Id.*) Further, Relator points out that a signatory for the entity submitting the cost report had to "certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." (*Id.*) Later, Relator alleges that Omnicare does in fact submit, or cause to be submitted, cost

reports containing certifications of compliance. (*See, e.g., id.* ¶¶ 382, 388.)

***18** There is an important distinction to be drawn between enrollment agreements and cost reports. Defendants contend that forward-looking promises to comply cannot amount to false certifications and that Medicare and Medicaid Enrollment Agreements only contain forward-looking promises.

a. *Whether Certifications Contained in Enrollment Agreements Suffice*

There is little serious debate as to whether the certifications contained within enrollment forms amount to promises to comply in the future. As the Court reads Relator's recitation thereof, they do. Relator alleges that Medicare Enrollment Agreements require that providers "certify that they understand that 'payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with ... the Federal anti-kickback statute.' " (*Id.* ¶ 245.) Medicaid Enrollment agreements, Relator avers, generally take a similar form. (*Id.* ¶¶ 250–77.)

As for whether their forward-looking nature disqualifies those certifications from serving as the "false certifications" necessary to state a FCA claim, the case law is not abundantly clear. At least two courts within this district have permitted the use of enrollment agreements. Most recently, the *Parikh* court sanctioned the use of "Medicare enrollment applications." *Parikh,* 977 F.Supp.2d at 664. It did not address the prospective nature of the certification contained therein. Another court authorized reliance on enrollment agreements, provided that, "at the time [the promise] was made the promisor had no intent to perform it." *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 20 F.Supp.2d 1017, 1036 (S.D.Tex.1998). The Court believes this issue demands greater scrutiny than the *Parikh* court applied. Further, it is wary of stretching the TAC so far as to read it to include an allegation that Defendants never intended to keep the commitments made in the enrollment forms. Accordingly, it cannot rely solely on *Parikh* or *Thompson* in allowing claims premised upon certifications contained within enrollment agreements to move forward.

The Eleventh Circuit in *McNutt ex rel. United States v. Haleyville Med. Supplies, Inc.,* 423 F.3d 1256 (11th Cir.2005) held that enrollment forms sufficed. It explained that failure to comply with the certification therein "disqualified [defendants] from receiving payment as part of a Medicare program" and that, "[w]hen a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the Act, for its submission of those false claims." *Id.* at 1259. Defendants here attempt to distinguish *McNutt* on the grounds that "there is no allegation in this case that Omnicare has ever been disqualified from participating in the Medicare program" (Doc. No. 139 at 12), assuming that one's disqualification from the program must be the result of an official determination by the Government. But there was no allegation of that sort in *McNutt,* either; rather, the Eleventh Circuit seemed to assume that violators of government regulations are automatically disqualified from future participation, regardless of whether the government intervenes and formally disqualifies them. Relying on *McNutt,* the court in *United States ex rel. Osheroff v. Tenet Healthcare Corp.,* No. 09–22253–CIV, 2013 WL 1289260 (S.D.Fla. Mar.27, 2013) reached the same result. It explained that defendant's "promise to comply with the Anti–Kickback Statute ... didn't merely gain Tenet entrance into the Medicare program; its promise was also a 'prerequisite [ ] and the *sine qua non* of federal funding.' " *Id.* at *4 (quoting *United States ex. rel. Hendow v. University of Phoenix,* 461 F.3d 1166, 1172 (9th Cir.2006)). The *Osheroff* court added that, "[i]f that weren't the case, and Tenet's promise of future compliance was nothing more than just that—a promise that didn't affect Tenet's standing to seek payment from Medicare—healthcare providers like Tenet 'would be virtually unfettered in [their] ability to receive funds from the government while flouting the law.' " *Id.* (quoting *Hendow,* 461 F.3d at 1176.)

***19** Several courts have read *McNutt* as endorsing an implied false certification theory. *See, e.g., United States ex rel. Freedman v. Suarez–Hoyos,* 781 F.Supp.2d 1270, 1278 (M.D.Fla.2011). That theory would hold more or less that, in signing the enrollment agreement, a provider both promises ongoing compliance with the AKS and is put on notice that future payments are conditioned on keeping that promise. As a result, when the provider subsequently seeks payment, it is implicitly certifying that it kept that promise to comply with the AKS. As the Fifth Circuit has put it, "[t]he implied-certification theory of liability under the FCA 'is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.' " *Steury,* 625 F.3d at 268 (quoting *Mikes v. Straus,* 274 F.3d 687, 699 (2d Cir.2001)); *see also Ebeid ex rel. United States v. Lungwitz,* 616 F.3d 993, 998

(9th Cir.2010) ("Implied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim."). The implied-certification theory has been adopted, in at least some form, by a majority of the federal courts of appeals. *See Mikes,* 274 F.3d at 699–700 (Second Circuit); *United States ex rel. Wilkins v. United Health Grp., Inc.,* 659 F.3d 295, 306 (3d Cir.2011); *United States ex rel. Augustine v. Century Health Servs., Inc.,* 289 F.3d 409, 415 (6th Cir.2002); *Ebeid,* 616 F.3d at 996–98 (Ninth Circuit); *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.,* 543 F.3d 1211, 1217 (10th Cir.2008); *McNutt,* 423 F.3d at 1259 (Eleventh Circuit); *United States v. Sci. Applications Int'l Corp.,* 626 F.3d 1257, 1266, 1269 (D.C.Cir.2010).[11]

But the Fifth Circuit has not yet chosen a side. *See Steury,* 625 F.3d at 268–69. In this Court's opinion, there is good reason for it to embrace the implied false certification theory. As the Third Circuit explained when it opted to do the same, the implied false certification theory "gives effect to Congress' expressly stated purpose that the FCA should 'reach all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services,' " *Wilkins,* 659 F.3d at 306 (quoting S.Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274)) and it finds support in the language and structure of the Act, *id.* In fact, "the text of the FCA does not exhibit an intent to limit liability in" the manner Defendants here suggest. *Hutcheson,* 647 F.3d at 387. And while the Court is mindful that the implied false certification theory should not be stretched too far, it supports allowing the implied false certification theory in cases such as this one. Defendants are alleged to have signed a document that states in no uncertain terms that payment of future claims is conditioned upon compliance with the AKS. That document made clear that compliance was "a *sine qua non* of receipt of state funding." *United States ex rel. Hopper v. Anton,* 91 F.3d 1261, 1267 (9th Cir.1996). Thus, where, like here, it is fairly apparent from the face of the complaint that "if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims," *Wilkins,* 659 F.3d at 307, application of the implied false certification theory would not unduly expand FCA liability or do violence to the Act's text, structure, or purpose.

***20** Thus, because the Court is persuaded that adopting the implied false certification theory is appropriate in the circumstances presented by this case—other courts have found that the language found in the enrollment agreements "comports with even the most parsimonious application of the implied certification theory," *United States ex rel. Pogue v. Diabetes Treatment Centers of Am.,* 565 F.Supp.2d 153, 159 (D.D.C.2008) (internal quotation marks omitted)—the Court denies the motion to dismiss as to claims arising out of certifications contained in enrollment agreements. The Court finds the legion of cases endorsing the use of enrollment agreements and embracing the application of an implied false certification theory more persuasive than the three Northern District of Illinois cases that Defendants cite for the proposition that forward-looking promises can never qualify as false certifications. *See United States ex rel. Kennedy v. Aventis Pharm., Inc.,* 610 F.Supp.2d 938, 946 (N.D.Ill.2009); *United States v. Ukranian Vill. Pharmacy, Inc.,* No. 09 C 7891, 2013 WL 5408573, at *4 (N.D.Ill. Sept.26, 2013); *United States ex rel. Wildhirt v. AARS Forever, Inc.,* No. 09 C 1215, 2011 WL 1303390, at *5 (N.D.Ill. Apr.6, 2011).

Still, wary of the adage that bad facts make bad law, and because the Court here embraces a theory of liability that has not yet been sanctioned by the court of appeals, upon the development of a more complete factual record, the Court is willing to reconsider this segment of its ruling.

b. *Whether Certifications Contained in Cost Reports Pass Muster*

As for certifications contained within cost reports, the Court has much less trouble finding them sufficient. Relator points to *Parikh* for that proposition, and for good reason. There, the court denied dismissal, for failure to allege false certification, of a complaint not materially different from the TAC. In *Parikh,* Defendants had argued that dismissal was compelled by *Nunnally,* 519 F. App'x 890, in which relator's only certification-related allegation was that defendant "periodically either certif[ied] in writing or impliedly certif[ied] to the Medicare program that it complied with all of Medicare's program rules, regulations and laws applicable thereto." *Id.* at 894. In fact, Nunnally conceded that "he ha[d] *no knowledge* of any expressed certification by WCCH." *Id.* at 894 n. 6 (emphasis in original). The *Parikh* court rejected defendant's comparison to *Nunnally* and held that "[t]he complaint provides extremely detailed allegations concerning how Citizens allegedly certified its compliance with the AKS." *Parikh,* 977 F.Supp.2d. at 664. Parikh had alleged that defendants

> CMC and Brown falsely certified in the CMS annual cost reports in 2006, 2007, 2008, 2009, 2011, and 2012, that the services identified in the reports were provided in compliance with such laws and regulations, including the Anti–Kickback and Stark Acts, despite knowing at the time that they were violating the Anti–Kickback and Stark Acts.

***21** (Doc. No. 49 ¶ 20 in Case No. 6:10–cv–00064.) Likewise, the *Parikh* complaint asserted that

> To conceal their unlawful conduct and avoid refunding payments made on these false claims, CMC and Brown also knowingly and falsely certified to the Government in 2006 through 2013, in violation of the FCA, that the services identified in their CMS annual cost reports were provided in compliance with federal law, including the prohibitions against kickbacks, illegal remuneration to physicians, and improper financial relationships with physicians. The false certifications, made with each annual CMS cost report submitted to the Government between 2006 and 2013, were part of CMC and Brown's unlawful scheme to defraud Medicare and other governmental healthcare programs and circumvent the Anti–Kickback and Stark Acts.

(*Id.* ¶ 65.) Other than listing one-by-one the years in which false certifications were made—and the Court does not believe that doing so is particularly illuminating for annual cost reports, which ostensibly are filed each year—the Parikh complaint seems to have offered little more than that which is operative here.[12]

The Court acknowledges that there remain unanswered questions regarding whether the (allegedly false) certifications at issue were in fact conditions of payment and that, at first blush, these seem to be questions of law ripe for disposition on a motion to dismiss. But Fifth Circuit precedent dictates otherwise. In *Gonzalez v. Fresenius Med. Care N. Am.,* 689 F.3d 470 (5th Cir.2012), the Fifth Circuit rejected the Government's assertion that "the district court erred in treating the question of whether the cost reports were a condition of payment as a question of fact," *id.* at 476 n. 6, noting that in *Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, the court "den [ied] defendants' 12(b)(6) motions as they relate to this issue and remand[ed] to the district court for further factual development." *Id.* at 903. It may well be that, in the final analysis, "cost reports" and other certifications relied upon by Relator "present a difficult basis for FCA liability," *Gonzalez,* 689 F.3d at 475 (5th Cir.2012),[13] but the Court is not convinced that Relator has failed to state a claim upon which relief can be granted or that Complaint fails to comport with Rule 9(b)'s particularity requirement.[14]

*3. Whether Relator Has Alleged Presentment*

As the Court sought to make clear above in its explication of Rule 9(b), Relator "must also establish that claims rendered fraudulent by an underlying AKS violations were 'presented to the Government.' " *Parikh,* 977 F.Supp.2d at 665 (quoting 31 U.S.C. § 3729(a)(1)(A–C)). As the court noted in *Parikh, "Grubbs* establishes that Relators need not identify particular claims resulting from the kickback scheme." *Id.* (quoting *Grubbs,* 565 F.3d at 190). That is because "requiring a relator to plead the 'exact dollar amounts, billing numbers, or dates' prior to discovery ... would be 'significantly more than any federal pleading rule contemplates.' " *Id.* (quoting *Grubbs,* 565 F.3d at 190). Instead, "[a]s long as Relators plead with particularity that [Defendants] made kickbacks with the intent of inducing referrals, and they plead 'particular details of a scheme ... paired with reliable indicia that lead to a strong inference that claims were actually submitted,' the separate elements of the AKS and FCA are satisfied." *Id.* (quoting *Grubbs,* 565 F.3d at 190).

***22** The Court here is persuaded by Relator's argument that "this fraud is built around the unique Medicare and Medicaid reimbursement structures in place in SNFs, which are dominated by such enrollees. Stated differently, the kickbacks exist *as a result* of the SNFs' tender of claims and Omnicare's failure to collect the Part A funds." (Doc. No. 137 at 40.) Put yet another way, "because the scheme executed is specific to government programs, there can be no doubt of the Government's injury." (*Id.*) Where the underlying allegation is that Omnicare forgives debts related to one government program in order to win business arising out of another government program, the obvious implication is that false claims will be submitted, as Relator has alleged. (*See* Doc. No. 97 ¶¶ 409–425.) The rest of the scheme, which has been sufficiently alleged, would make no sense at all without presentment of false claims. As a result, those allegations (discussed above) are sufficient to provide reliable indicia of false claims, and the Complaint may proceed.

**B. 31 U.S.C. § 3729(a)(2) (former); 31 U.S.C. § 3729(a)(1)(B) (current)**

Relator has also brought a claim under the former 31 U.S.C. § 3729(a)(2), which has been recodified as § 3729(a)(1)(B), and which prohibits "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a

false or fraudulent claim." Defendants have not independently argued for dismissal of this claim, and the Court does not see how it could fail if the aforementioned claims brought under the former § 3729(a) (1) succeed. Consequently, to the extent Defendants have moved to dismiss this claim, that Motion is likewise **DENIED.**

**C. Retaliation (31 U.S.C. § 3730(h))**

*1. Relevant Factual Allegations*

In her role as Omnicare's collections manager, Relator[15] gained extensive knowledge of the hefty balances that were often past due. (Doc. No. 97 ¶¶ 283, 287–99, 304–16.) She has alleged that she reported what she had discovered to her supervisor, Richard Richow, and that he "reminded her that Omnicare makes a great deal of money from the Medicaid ... beneficiaries at those facilities and said that Omnicare did not want to risk losing that income." (*Id.* ¶ 313.) Further, when Relator expressed her unqualified reservations —"But that's inducement!"-Richow agreed and remarked (the Court assumes glibly) that Omnicare's Executive Director of Pharmacy in New York would be the "first to go to prison." (*Id.*) In a separate incident, Relator met with pharmacy managers and "explained that intentionally failing to collect amounts due for pharmaceuticals and services provided to Medicare Part A beneficiaries constituted illegal inducement." (*Id.* ¶ 316.) Ruscher says that, "[i]n repeatedly warning her superiors that Omnicare was engaged in fraudulent activity, Ruscher did not mince words." (*Id.* ¶ 322.)

If it had not begun sooner, Relator's fall from grace within Omnicare certainly began in earnest in June 2008. During that month, Relator asked one national account, Five Star, to pay its debts. (*Id.* ¶ 324.) Omnicare's COO directed her to halt her collections efforts and instructed her to "tread lightly" as Omnicare sought to purchase other Five Star pharmacies. (*Id.*) Soon thereafter, on July 1, Relator was transitioned to a new role within the organization, becoming the National Litigation Manager. (*Id.* ¶ 325.) In that role, she sought to keep track of how much Omnicare was spending on collections-related litigation, but was quickly informed by David Gemunder, son of Omnicare CEO Joel Gemunder and a partner at Omnicare's outside counsel, that she did not need such information. (*Id.* ¶ 325.) A week or so later, attorneys from another firm approached Relator, told her that "they had been hired by Omnicare's in-house counsel to find the 'disconnect' between Ruscher and its national counsel," and "interrogate[d] Ruscher regarding a seemingly random selection of her past actions." (*Id.* ¶¶ 326–27.) At a later meeting held in Las Vegas, those attorneys insinuated to Relator that they believed she was having an affair with an attorney she had hired to conduct collections, leaving her "deeply offended." (*Id.* ¶ 329.)

***23** Relator took a long-scheduled vacation after the Las Vegas meeting and, upon returning to her office on Sunday, August 17, 2008, could not access her office computer. (*Id.* ¶ 330.) She was terminated the next day. (*Id.*) Relator alleges that, because she "exposed the illegal kickbacks being spent on the National Accounts and P–Hold facilities, and Omnicare's larger scheme to dominate the market ... Omnicare could not tolerate the threat [she] posed, and she was terminated." (*Id.* ¶ 3 31.)

These allegations give rise to her retaliation claim.

*2. Legal Standard*

"The whistleblower provision of the False Claims Act, 31 U.S.C. § 3730(h), encourages employees with knowledge of fraud to come forward by prohibiting retaliation against employees who assist in or bring *qui tam* actions against their employers." *United States ex rel. Patton v. Shaw Servs., LLC,* 418 F. App'x 366, 371 (5th Cir.2011) (citing *Robertson v. Bell Helicopter Textron, Inc.,* 32 F.3d 948, 951 (5th Cir.1994)). Specifically, § 3730(h) (1) prohibits employers from retaliating against Relator for undertaking "lawful acts ... in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter." To state a claim for FCA retaliation, Relator must allege that she "engaged in activity protected under the statute, that h[er] employer knew [s]he engaged in protected activity, and that [s]he was discharged because of it." *Patton,* 418 F. App'x at 371–72 (citing *Robertson,* 32 F.3d at 951). FCA retaliation does not sound in fraud and thus need not be pleaded with particularity; Defendants do not argue otherwise.

*3. Analysis*

a. *Whether Relator Has Alleged That She Engaged in Protected Activity*

As another district court in this circuit recently explained, "[t]o engage in protected activity under the Act, an employee need not 'have filed an FCA lawsuit or [ ] have developed a winning claim at the time of the alleged retaliation.' " *United States ex rel. George v. Boston Scientific Corp.,* 864 F.Supp.2d 597, 604–05 (S.D.Tex.2012) (quoting *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.,* 360 F.3d 220, 236

(1st Cir.2004) and citing *United States ex rel. Yesudian v. Howard Univ.,* 153 F.3d 731, 741 (D.C.Cir.1998); *Schuhardt v. Washington Univ.,* 390 F.3d 563, 567 (8th Cir.2004)). Rather, "an employee's actions must be aimed at matters that reasonably could lead to a viable claim under the Act" or "matters demonstrating a 'distinct possibility' of False Claims Act litigation." *Id.* at 605 (collecting cases). Synthesizing cases across the circuits, the *George* court explained that either formulation is "satisfied when '(1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government.' " *Id.* (quoting *Hoyte v. Am. Nat. Red Cross,* 518 F.3d 61, 71 (D.C.Cir.2008)). Both "fraud" and "against the government" are important. It is certainly not enough to merely complain of an employer's inefficiency or incompetence, *Patton,* 418 F. App'x at 372 ("Mere criticism of Shaw's construction methods, without any suggestion that Patton was attempting to expose illegality or fraud within the meaning of the FCA, does not rise to the level of protected activity."), and it is equally unavailing to assert that a non-governmental third party is the victim of fraudulent conduct, *George,* 864 F.Supp.2d at 606 ("the focus is on whether the internal complaint 'allege[s] fraud on the government' " (quoting *McKenzie v. BellSouth Telecommunications, Inc.,* 219 F.3d 508, 516 (6th Cir.2000))).

***24** Relator has alleged that she believed Omnicare guilty of "inducement," that she knew "inducement" was illegal, and that she alerted her supervisor, Richow, and pharmacy managers to those beliefs. (*See* Doc. No. 97 ¶¶ 313, 316.) The thrust, then, of Relator's allegations is that she believed Omnicare had violated the AKS. It is also clear, in view of the TAC as a whole, that she was highly knowledgeable of how Omnicare's business was closely tied to government programs, specifically Medicare and Medicaid. Thus, it seems quite plausible that Relator's actions were "calculated to, or reasonably could, lead to a viable FCA case." *United States ex rel. Dyson v. Amerigroup Texas, Inc.,* No. CIV.A. H–03–4223, 2005 WL 2467689, at *2 (S.D.Tex. Oct.6, 2005) (Ellison, J.).

Defendants argue that "Relator has not alleged a single instance where she complained or reported that Omnicare was submitting or causing fraudulent claims for payment to the government" and that "[s]he also does not allege that she investigated fraudulent claims for payment, or that she attempted to stop any purported FCA violations." (Doc. No. 120 at 39.) As an initial matter, relators are not required to try to stop fraud in order to state a claim for retaliation.[16] Further, Defendants' attempt to cherry-pick what it is that Relator needs to have investigated or reported to her employer—they contend, in essence, that presentment triggers protection; inducement does not—is inappropriate.

Defendants' argument boils down to a contention that, even where the underlying FCA allegation is based upon AKS violations and false certification, Relator nevertheless must have taken action regarding the presentment to the Government of false claims. That assertion does not withstand scrutiny. First, it would be strange if Relator was required to investigate or report something that, even to this day, she need not have pleaded in order to survive a motion to dismiss. *See supra* Section III.A.3. Second, if Defendants' proposed rule is the right one, then one of two things must be true. Either Relator was required to have exposed the kickbacks and false certifications *in addition to* presentment of false claims, or alternately, investigating/reporting AKS violations was irrelevant and the only way she could have triggered the FCA's retaliation protection is to have alerted her employer to the presentment of fraudulent claims. The former cannot be true because to so require would force Relator to "develop a winning *qui tam* suit," *Dyson,* 2005 WL 2467689, at *2, and the cases make clear that she need not have done so. And, the latter is nonsensical, because in that scenario, she either knows about kickbacks and does not say anything, and so is rewarded for being less than forthcoming in what she told her employer, or she has no idea that the inducements have taken place, and thus does not know why the claims were fraudulent at all. In that final scenario, she would be protected for blindly claiming fraud without any real basis for doing so. The rule Defendants would have the Court apply cannot bear the weight they place upon it.

***25** In short, Relator's allegations that she alerted her supervisor and various pharmacy managers to inducement satisfies her obligation to have pleaded that she engaged in protected activity.

b. *Whether Relator Has Alleged That Her Employer Had Knowledge of Her Protected Activity*

Not only must Relator have engaged in protected activity, but "[t]he employer must be on notice that the employee is investigating fraud." *George,* 864 F.Supp.2d at 607. " 'Notice can be accomplished ... by any action which a factfinder reasonably could conclude would put the employer on notice that litigation is a reasonable possibility.' " *Id.* at 608 (quoting *United States ex rel. Williams v. Martin–Baker Aircraft Co.,* 389 F.3d 1251, 1262 (D.C.Cir.2004)). "Courts

have found this notice prong satisfied based on allegations that the employee complained directly to her supervisors." *Id.* (citing *Harrington v. Aggregate Indus. Ne. Region, Inc.,* 668 F.3d 25, 32 (1st Cir.2012); *United States ex rel. Sarafoglou v. Weill Med. College of Cornell Univ.,* 451 F.Supp.2d 613, 624–25 (S.D.N.Y.2006)). Importantly, though, while " '[i]nternal reporting has been held to constitute protected activity ... if an employee wants to impute knowledge to the employer for purposes of the second prong of the analysis, he must specifically tell the employer that he is concerned about possible fraud.' " *Id.* (quoting *United States ex rel. Smith v. Yale Univ.,* 415 F.Supp.2d 58, 105 (D.Conn.2006)). Still, "no 'magic words'—such as 'illegal' or 'unlawful'—are necessary to place the employer on notice of protected activity." *Id.* (quoting *Fanslow v. Chicago Mfg. Ctr. ., Inc.,* 384 F.3d 469, 484 (7th Cir.2004)).

In the instant case, this second requirement is not particularly distinguishable from the first, given that Relator's protected activity was the very act of alerting higher-ups in the corporation that she was aware of potentially illegal kickbacks. The Court finds it sufficient that Relator has alleged that she alerted Richow and pharmacy managers to potentially fraudulent activity.[17]

c. *Whether Relator Has Alleged Causation*

Relator's final duty is to plead that her termination was motivated by her protected activity. *George,* 864 F.Supp.2d at 609 (citing *Shekoyan v. Sibley Int'l,* 409 F.3d 414, 422(D.C.Cir.2005)). This is akin to the causal link step of Title VII's *McDonnell Douglas* analysis. "The showing necessary to demonstrate the causal-link part of the *prima facie* case is not onerous; the plaintiff merely has to prove that the protected activity and the negative employment action are not completely unrelated." *Dyson,* 2005 WL 2467689, at *3 (internal quotation marks omitted). "[T]emporal proximity alone, when very close, can in some instances establish a *prima facie case* of retaliation." *Strong v. Univ. Healthcare Sys., LLC,* 482 F.3d 802, 808 (5th Cir.2007).

***26** The Court is satisfied that Relator has met her burden. She has not pleaded exactly when it was that she alerted Richow that she believed inducement was taking place, but she has averred that she had her conversation with pharmacy managers in May 2008 and sought to collect from Five Star in June 2008. In the next few months, she was transitioned out of her old job, "interrogated" about her earlier activities, accused of having an extramarital affair, and finally, terminated. These other occurrences serve as probative indicia that she had fallen out of favor with her employer and, when considered in concert with the close timing between her protected activity and her termination, convince that Court that Relator has sufficiently alleged a causal connection. Relator's retaliation claim may go forward.

**D. Conspiracy**

As another means of combatting false claims, § 3729(a)(1)(c)—previously § 3729(a)(3)—imposes liability upon one who "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid."[18] The Fifth Circuit has held "that to prove a False Claims Act conspiracy, a relator must show '(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by [the Government] and (2) at least one act performed in furtherance of that agreement.' " *Grubbs,* 565 F.3d at 193 (quoting *United States ex rel. Farmer v. City of Houston,* 523 F.3d 333, 343 (5th Cir.2008)). FCA conspiracy claims must meet Rule 9(b)'s particularity requirement, both with respect to the agreement and the overt acts taken in furtherance thereof. *Id.* (citing *FC Inv. Group LC v. IFX Markets, Ltd.,* 529 F.3d 1087, 1097 (D.C.Cir.2008)).

Defendants contend that the TAC "is completely devoid of any facts regarding how Omnicare or its customers entered into an actual agreement for the purpose of defrauding the government." (Doc. No. 120 at 29.) But, of course, Relator is not required to plead (or even, at the end of the day, prove) the manner in which the agreement came into being, only that an agreement did in fact exist. *Cf. United States ex rel. Jamison v. McKesson Corp.,* No. 208CV214 SA DAS, 2009 WL 3176168, at *14 (N.D.Miss. Sept.29, 2009) (explaining that traditional conspiracy principles apply to False Claims Act conspiracy claims and that under those principles " '[e]xpress agreement among all the conspirators is not necessary to find the existence of a civil conspiracy,' " and instead " '[a]ll that must be shown is that there was a single plan, that the alleged coconspirator shared in the general conspiratorial objective, and that an overt act was committed in furtherance of the conspiracy' " (quoting *United States v. Murphy,* 937 F.2d 1032, 1039 (6th Cir.1991))), *modified on other grounds on reconsideration,* 2:08CV214–SA–DAS, 2010 WL 1223876 (N.D.Miss. Mar.25, 2010). And the nature of Relator's FCA allegations is such that an agreement between Omnicare and its customers is the only way in which the scheme makes any sense. That is, the idea that Omnicare "would forego payment for Medicare Part A related services and the recipient SNFs

would refer Medicaid/Medicare Part D patients to Omnicare" and then that "the SNFs would represent to Medicare in cost reports that they were paying for the free or greatly discounted drugs"[19] only makes any sense at all if there was some agreement between Omnicare and the SNFs. Taking Relator's allegations as true, there is no possible explanation for either Omnicare's or the SNF's actions *other than* an agreement between the parties. This is the quintessential illustration of a case in which the agreement can be "naturally inferred from the allegations ." *Grubbs,* 565 F.3d at 194; *see also Nunnally,* 2012 WL 1866586, at *2 ("An agreement may be inferred when it is a natural consequence of the factual allegations.").

***27** Having decided that Relator has sufficiently (and with particularity) pleaded the existence of an agreement, it is not particularly difficult to arrive at the conclusion that she has also pleaded overt acts. Setting the forgiveness of debt to one side, as there is at least an argument to be made that it is more omission than act, Omnicare officials actively sought to stop Relator from making collections. (Doc. No. 97 ¶¶ 301–03, 324.) The Court is satisfied by Relator's allegations of overt acts and thus will allow the conspiracy claim to proceed.

**E. Reverse False Claims**

Just as the False Claims Act prohibits the use of false records or statements to induce the government to make a certain payment, it likewise prohibits the use of false records or statements to conceal an obligation to pay money to the government. The so-called Reverse False Claims Act subjects to liability anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." *See* 31 U.S.C. § 3729(a)(7) (version operative when complaint was filed).[20] That obligation to the Government must not be "potential" or "contingent" upon any sort of "intervening discretionary governmental acts." *United States ex rel. Marcy v. Rowan Companies, Inc.,* 520 F.3d 384, 391 (5th Cir.2008). Worthy of emphasis is the Act's imposition of liability upon he who *"causes* a false statement to be made" just as it does he who makes the false statement. *United States v. Caremark, Inc.,* 634 F.3d 808, 815 (5th Cir.2011); *see also Riley,* 355 F.3d at 378 ("The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud, without regard to whether that person has direct contractual relations with the government." (internal quotation marks omitted)).

As the Court understands the TAC, Relator's §§ 3729(a)(2) and (a)(7) claims represent two sides of the same coin. That is, her theory of liability on the (a)(2) claims is that SNFs used Medicare and Medicaid cost reports to get claims paid, and that those claims were false because they were tainted by kickbacks paid by Omnicare (thus also subjecting Omnicare to liability). Conversely, her theory of liability on the (a)(7) claims is that the SNFs used those same reports to conceal that the SNFs were duty-bound to reimburse the Government for all the claims it paid, because those claims, tainted by Omnicare's kickbacks, were false. Put differently, insofar as "[i]n a reverse False Claims Act suit, there is no improper payment by the government to a defendant, but rather there is an improper reduction in the defendant's liability to the government," *Marcy,* 520 F.3d at 390, the liability to the Government at issue arises because of the § 3729(a)(2) violations. Viewed yet another way, so far as the Court can tell, the same set of operative facts give rise Relator's claims under both sections.

***28** Mindful that the Reverse False Claims Act's "purpose was not to provide a redundant basis to state a false statement claim under subsection (a)(2)," *United States ex rel. Spay v. CVS Caremark Corp.,* 913 F.Supp.2d 125, 171–72 (E.D.Pa.2012) (internal quotation marks omitted), the Court cannot allow the Reverse False Claims Act claims to proceed. Indeed, other courts that have confronted similar allegations have drawn the same conclusion. For instance, in *United States ex rel. Thomas v. Siemens AG,* 708 F.Supp.2d 505 (E.D.Pa.2010), Relator "argue[d] that SMS demanded payment based on a fraudulently induced contract each time it requested payment," that, as a result, "each invoice was inflated, imposing an affirmative obligation on SMS to refund payments it improperly received from the government," and that "[b]ecause SMS did not refund the payments, it avoided or decreased its obligation to the government." *Id.* at 514. The court realized that relator was "essentially alleging that SMS failed to refund the false claims that the government paid" and that, in doing so, "[h]e [wa]s merely recasting his false statement claim under § 3729(a)(2)." *Id.* The court therefore dismissed his § 3729(a) (7) claim. Likewise, in *United States ex rel. Taylor v. Gabelli,* 345 F.Supp.2d 313 (S.D.N.Y.2004), "the reduction in money owed to the Government" was "the very same money that the defendants will procure from the U.S. Treasury (as a government payment), according to Taylor's claims under either section 3729(a) (1) and (a)(2)." *Id.* at 338. Thus, the court held that, "[b]ecause Taylor's allegations state a claim under sections 3729(a)(1) and (2), they cannot also form the basis for a claim under subsection

(a)(7)" and it dismissed the latter claim. *Id.* at 339; *see also United States v. HCA Health Servs. of Oklahoma, Inc.,* No. 3:09–CV–0992, 2011 WL 4590791, at *8 (N.D.Tex. Sept.30, 2011) (same). The Court here does likewise.[21]

**F. State Claims**

Relator has brought claims under the laws of twenty-one states and the District of Columbia. For the reasons discussed above, Defendants' Rule 12(b)(6) and Rule 9(b) challenges are largely denied, though, as with the federal claims, the Court dismisses the state claims that arose before 2005 or after 2008. Below, it addresses Defendants' remaining challenges in turn.

*1. Failure to File in State Court*

Defendants assert that California, Delaware, the District of Columbia, Florida, Indiana, Louisiana, and Massachusetts require that Relator file her complaint in state court and that Relator has failed to allege that she did so. *See* Cal. Gov't Code § 12652(c)(2); 6 Del.Code § 1201(c); D.C.Code § 2–381.03(b)(2); Fla. Stat. Ann. § 68.083(3); Indiana Code §§ 5–11–5.5–3(h), 5–11–5.5–4(a)(2); La.Rev.Stat. § 46.439.1(A); Mass. Gen. Laws ch. 12 § 5C(2). As Defendants acknowledge, however, their primary support for that position, *United States ex rel. Galmines v. Novartis Pharm. Corp.,* No. CIV.A. 06–3213, 2013 WL 2649704, at *13 (E.D.Pa. June 13, 2013), has since been withdrawn and amended. *See* No. CIV.A. 06–3213, 2013 WL 5924962 (E.D.Pa. Nov.5, 2013). Absent any additional arguments in support of dismissing these state claims on this particular basis, the motion is **DENIED.**

*2. Failure to Provide Information to Specified State Officials or Entities*

***29** Defendants argue that each state statute under which Relator has pressed a claim requires that she provide certain relevant information to specific state government officials or entities on or around the time she filed suit—and that she failed to do so. *See* Cal. Gov't Code § 12652(c)(3); 6 Del.Code § 1203(b)(2); D.C.Code § 2–381.03(b)(3); Fla. Stat. § 68.083(3); Ga.Code Ann. § 49–4–168.2(c)(1); Haw.Rev.Stat. § 661–25(b); 740 Ill. Comp. Stat. 175/4(b)(2); Ind.Code § 5–11–5.5–4(c); La.Rev.Stat. Ann. § 46:439.2(a)(2); Mass. Gen. Laws ch. 12 § 5(C)(3); Mich. Comp. Laws § 400.610a(2); Mont.Code § 17–8–406(2); Nev. Rev. Stat § 357.080(5); N.J. Stat. Ann. § 2A:32C–5(d); N.M. Stat. § 27–14–7(C); N.Y. St. Fin. § 190(b); 63 Okl. St. Ann. § 5053.2(b)(2); R.I. Gen. Laws § 9–1.1–4(b)(2); Tenn.Code Ann. § 71–5–183(b)(2); Tex. Hum. Res.Code Ann. § 36.102(a); Va.Code Ann. § 8.01–216.5(b); Wisc. Stat. Ann. § 20.931(5)(b). Relator contends that she is not actually required to plead compliance with these statutes, but to the extent that she was, she was permitted to do so generally. On this last point, Defendants do not argue otherwise.

Defendants cite two cases for the proposition that failure to plead compliance with the various state service mandates warrants dismissal. The first is not helpful. In *United States ex rel. Bogart v. King Pharm.,* 414 F.Supp.2d 540 (E.D.Pa.2006), where Relator had in fact failed to serve state governments, the Court granted a motion for summary judgment *brought by those states* because "Relator's failure to adequately serve the States ... frustrated the purposes of the States' statutes and prejudiced the States accordingly." *Id.* at 545. The second, *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.,* 906 F.Supp.2d 1264, 1278 (N.D.Ga.2012), offers the holding that Defendants would like this Court to adopt but not reasoning that it can accept. The *Saldivar* court dismissed a raft of state law claims for failure to plead compliance with state law requirements just like—some, identical to—those at issue here. But the cases it relied upon to reach that conclusion are not in accord. In *LaPosta v. Borough of Roseland,* 309 F. App'x 598 (3d Cir.2009), the Third Circuit affirmed dismissal because plaintiff had not actually served *the defendant* with a notice of claim as he was required to do. The case had nothing to do with pleading requirements. *Id.* at 603. Likewise, in *Edwards v. City of New York,* No. 10–CV–OI047 ARR LB, 2011 WL 5024721 (E.D.N.Y. Oct.18, 2011), the court considered whether plaintiff had in fact complied with the requirement that she notify the municipality soon after a claim *against it* arose.[22] *Id.* at *6. It declined to adopt defendants' position that failure to plead compliance necessitates dismissal. *Id.* Finally, in *Tatum v. City of New York,* No. 06–CV–4290PGGGWG, 2009 WL 1748044 (S.D.N.Y. June 19, 2009), the court acknowledged that, where a state statute required plaintiff to plead that thirty days had elapsed since he had served defendant with a notice of claim, dismissal could be the appropriate response to plaintiff's failure to so plead, at least so long as defendant raised the argument in a timely fashion. *Id.* at *8.

***30** There are two primary reasons why the Court is unwilling to rely upon these cases. First, there is a standing issue lurking in the background. In each case, it was the party that had been most directly aggrieved by the procedural failure that sought dismissal. That is, in *Bogart,* it was the

states that had not been served that sought to dismiss Relator's claims and, in *La Posta, Edwards,* and *Tatum,* it was the municipal defendant, which had not been provided the notice to which it was entitled, that moved for dismissal. These cases do not answer the question whether Omnicare can seek to vindicate an injury that it did not suffer. Second, *Bogart, LaPosta,* and *Edwards* construed actual compliance with procedural requirements, not whether compliance had been pleaded, and *Tatum* examined whether a condition precedent had been pleaded because a state statute explicitly required as much. These cases do not suggest that pleading compliance is required absent a statutory directive to do so.

Thus, with both cases relied upon by Defendants set to the side, the Court declines to impose this pleading requirement upon Relator. The state statutes that Defendants allege Relator has failed to comply with require that Relator do something —serve or otherwise provide information to various states —contemporaneously with, or subsequently to, the filing of her Complaint. Thus, in practice, Relator would either need to plead compliance before she actually knows that she has done so, or she would have to plead that she *intends to comply.* Neither seems to be particularly meaningful. When this case reaches the summary judgment stage, Defendants may argue that Relator has failed to serve the state plaintiffs, if Defendants actually believe that to be the case, but for now, the Court declines to dismiss the state claims for failure to plead procedural compliance.[23]

*3. Retroactivity*

Next, Defendants assert that certain state false claims acts were enacted after Defendants' alleged wrongdoing began and cannot be applied retroactively. Because the Court has limited Relator's claims to a 2005–2008 timeframe, the Court need to address retroactivity for the Hawaii (effective 2000), Massachusetts (effective 2000), New Mexico (effective 2004), and Virginia (effective 2003) statutes. That leaves the Court to consider Georgia (effective May 24, 2007), Indiana (effective May 11, 2005), New Jersey (effective March 13, 2008), New York (effective April 1, 2007), Oklahoma (effective November 1, 2007), and Rhode Island (effective February 15, 2008).[24] Each of those statutes is silent on retroactivity.

While the parties debate the applicability of the Supreme Court's decisions in *Bradley v. Sch. Bd. of City of Richmond,* 416 U.S. 696, 94 S.Ct. 2006, 40 L.Ed.2d 476 (1974) and *Landgraf v. USI Film Products,* 511 U.S. 244, 114 S.Ct. 1483, 128 L.Ed.2d 229 (1994), as another court within this district noted when addressing this same issue, "the issue is whether *state* statutes should be given retroactive effect when the state legislatures did not provide any guidance. Thus, the court must consider how each state or locality at issue treats retroactivity issues." *United States ex rel. King v. Solvay S.A.,* 823 F.Supp.2d 472, 525 (S.D.Tex.2011), *order vacated in part on other grounds on reconsideration,* No. CIV.A. H–06–2662, 2012 WL 1067228 (S.D.Tex. Mar.28, 2012).

***31** Indeed, asked in *King* to determine whether state false claims acts applied retroactively, Judge Miller undertook an exhaustive analysis of the relevant state laws for each state that is at issue here, ultimately dismissing each with prejudice. This Court agrees with the *King* court's reasoning and therefore dismisses with prejudice all claims brought under the laws of Georgia, *see id.* at 526, Indiana, *see id.* at 527, New Jersey, *see id.* at 528, New York, *see id.* at 529, Oklahoma, *see id.* at 529–30, and Rhode Island, *see id.* at 530–31, that arose before the relevant state statutes became effective.

*4. Time–Barred Claims*

Defendants assert that certain of Relator's state law claims are time barred (Doc. No. 120 at 45 (pointing to four-and six-year statute of limitations)), but the Court's decision to limit her claims to the 2005–to–2008 period moots those arguments.

*5. Additional and Independent Bases*

Defendants have moved to dismiss the Georgia state law claims because there is no state law analogue to the federal AKS. (Doc. No. 120 at 45.) Regardless of that argument's merit, however, Relator has pleaded that Defendants' violations of the *federal* AKS triggered violations of the *state* false claims act (*see* Doc. No. 97 ¶¶ 504–05), and Defendants have not argued otherwise. Consequently, the Motion to Dismiss the Georgia claims on this basis is **DENIED.**

Defendants also argue for dismissal of the Texas state claims, at least those arising prior to May 4, 2007, because before that date, "Texas did not permit relators to pursue FCA claims without state intervention." (Doc. No. 120 at 45.) The *King* court considered, and rejected, this very argument and this Court is not inclined to disagree. As that court noted, the legislature amended the rule in question in 2007, allowing a Relator to proceed where the state has declined to intervene. *King,* 823 F.Supp.2d at 522. The amendment "appl[ied] 'only

to conduct that occur[ed] on or after the effective date ... of [the] Act.' " *Id.* (quoting Tex. Human Res.Code Ann. § 36.104 (Vernon Supp.2010) (Historical and Statutory Notes)). While defendant there, like Defendants here, would have liked the court to have read "conduct" as referring to the defendant's conduct that allegedly gave rise to liability, "[t]he 'conduct' discussed in section 36.104 is the State of Texas's election not to intervene." *Id.* Thus, because the state of Texas had filed its notice of non-intervention in 2009, the relevant conduct took place after the statute's amendment and relator could proceed without Texas' participation. *Id.* The same is true here. This suit was not filed until 2008 and thus Texas did not decline to intervene until sometime after the relevant statute was amended in 2007. Relator may thus press the claim without the assistance of the state and the Motion to Dismiss the Texas claims is therefore **DENIED.**

## IV. GEMUNDER'S MOTION TO DISMISS

***32** Defendant Joel Gemunder served as President and, later, CEO of Omnicare from 1981 to July 2010. (Doc. No. 97 ¶¶ 7, 218.) When Relator first filed this suit in November 2008, she did not name Gemunder, then still CEO, as a Defendant. (Doc. No. 1.) Nor did she add him as a party in December 2008, or September 2009, when she amended her complaint. (Doc. Nos.5, 13.) She also did not seek leave to add Gemunder in July 2008 when she sought to file the TAC. (Doc. No. 68.) Rather, she asserted that she did not intend to "raise [ ] new claims" (Doc. No. 88 at 2) and intimated that, at least with respect to amendments that did not rely on certain confidential documents, her primary purpose was to shore up her Complaint for a fight over its compliance with Rule 9(b), (Doc. No. 102 at 13, 20). In granting the Motion to Amend, the Court stated that Defendants could be dropped but did not have occasion even to consider whether they could be added. (*Id.* at 27.) Nevertheless, when the TAC was filed on September 6, 2013, Gemunder was named as a defendant. (Doc. No. 97.)

In adding Gemunder without first seeking leave to do so, Relator not only ran afoul of the Federal Rules of Civil Procedure, but she also violated the spirit, if not the letter, of the Court's order allowing her to file the TAC. "Although Rule 15 'evinces a bias in favor of granting leave to amend,' it is not automatic." *Matagorda Ventures, Inc. v. Travelers Lloyds Ins. Co.,* 203 F.Supp.2d 704, 718 (S.D.Tex.2000) (quoting *Dussouy v. Gulf Coast Inv. Corp.,* 660 F.2d 594, 598 (5th Cir.1981)). Rule 15(a)(2) required that Relator seek this Court's permission before filing the TAC, and it is clear from the written motion (Doc. No. 88 at 2), and from Relator's comments at this Court's hearing (Doc. No. 102 at 13, 20), that she did not request to add a new Defendant. Moreover, in granting leave to file the TAC, the Court relied upon Relator's representation that there would be no new claims and, by explicitly stating that Defendants could be dropped, signaled that it would at the very least want to hear more before it allowed the opposite. It is beyond cavil that the Court may strike claims that exceed the scope of its order granting leave. *See, e.g., Maisa Prop., Inc. v. Cathay Bank,* No. 4:12–CV–066–A, 2012 WL 1563938, at *2 (N.D.Tex. May 2, 2012) (striking defendant because it was "apparent to the court that Maisa's amended pleading exceed[ed] the scope of the" court's order and thus violated Rule 15(a)(2)); *Farac v. Sundown Energy, LP,* No. CIV.A. 06–7147, 2009 WL 2241329, at *3 (E.D.La. July 23, 2009) (granting motion to strike and/or dismiss because the court found "that Isla's Fourth Amended Complaint was filed in violation of the Court's May 26th minute entry, and in violation of LR 7.6E and Rule 15 of the Federal Rules of Civil Procedure"); *Benton v. Baker Hughes,* No. CV 12–07735 MMM MRWX, 2013 WL 3353636, at *3 (C.D.Cal. June 30, 2013), *DeLeon v. Wells Fargo Bank, N.A.,* 10–CV–01390–LHK, 2010 WL 4285006, at *3 (N.D.Cal. Oct.22, 2010). As such, Defendant Gemunder's Motion to Dismiss is **GRANTED.**

## V. CONCLUSION

***33** "[T]he FCA has grown, in fits and starts, into the government's chief weapon against fraud in connection with federal programs and expenditures" and "in practice most FCA enforcement efforts are initiated as private lawsuits brought pursuant to the FCA's *qui tam* provisions." David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation,* 112 Colum. L.Rev. 1244, 1270 (2012). *Qui tam* relators, then, play a central, if not vital, role, in the Government's enforcement apparatus. Still, because of the potential for relators to reap a phenomenal windfall and the attendant risk of abuse by professional relators, and in recognition of the fact that FCA cases can be particularly burdensome (and the successful ones particularly injurious) for defendants, more is required of the *qui tam* relator than almost any other litigant in federal court.[25] *See generally* Ni Qian, Note, *Necessary Evils: How to Stop Worrying and Love Qui Tam,* 2013 Colum. Bus. L.Rev. 594 (2013). A relator must generally be the first to file a suit making her particular allegations, must not base her action upon publicly disclosed information (or must be the original source of that information), and must plead with particularity in compliance with Rule 9(b). *See* 31 U.S.C. § 3730(e)(3);

*id.* § 3730(e)(4): Fed. R. Civ. P 9(b). An added wrinkle here is that Relator was (rightly) required to make her allegations using only her first-hand knowledge and ignoring documents obtained by the Government, and shared with her, during its investigation. (*See generally* Doc. No. 102.)

All of that is to say that Relator's Third Amended Complaint was required to meet an exceptionally high bar and has been subjected to intensive scrutiny—and for good reason. But upon careful consideration of that complaint, the meticulous briefing by the parties, and the voluminous, if not always coherent, case law on the subject, the Court determines that most of the Relator's claims pass muster. To review, Omnicare's Motion to Dismiss (Doc. No. 120) is **DENIED** as to Counts I and II in the TAC except with respect to claims that arose before 2005 and after 2008, for which it is **GRANTED.** The Motion is **DENIED** as to Counts III and IV. The Motion is **GRANTED** as to Count V. As for Counts VI–XXVII, those claims are likewise limited to the 2005–2008 timeframe and claims brought under the laws of the following states are **DISMISSED** to the extent they arose before the law's effective date: Georgia (effective May 24, 2007), Indiana (effective May 11, 2005), Montana (effective Oct. 1, 2005), New Jersey (effective March 13, 2008), New York (effective April 1, 2007), Oklahoma (effective November 1, 2007), and Rhode Island (effective February 15, 2008). Defendant Gemunder's Motion to Dismiss (Doc. No. 126) is **GRANTED.** Relator's Motion to Strike the TAC (Doc. No. 132) is **GRANTED.**

**IT IS SO ORDERED.**

**All Citations**

Not Reported in F.Supp.3d, 2014 WL 2618158, Med & Med GD (CCH) P 304,967

Footnotes

1 Less pressingly, Relator's Motion to Strike portions of her complaint (Doc. No. 132) is **GRANTED.** The Court did not consider those sections in its consideration of the Motion to Dismiss.

2 The False Claims Act was amended in 2009. Prior to those amendments, the provisions just quoted were codified at § 3729(a) (1), (2), and (7).

3 The Court here merely attempts to provide an overview of Relator's factual allegations; it addresses more specific contentions, as necessary, throughout its analysis. For the purposes of a motion to dismiss, the Court takes Relator's factual allegations as true. *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 556, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

4 It is Omnicare's 250 pharmacies which actually enter into contracts with SNFs. (Doc. No. 97 ¶ 285.)

5 Relator alleges that, "while federal regulations prohibit providers (such as nursing homes) from steering patients to particular pharmacies for the sake of profit, and while the choice theoretically belongs to patients, for all practical purposes it is still nursing homes that elect the pharmacy that will serve their residents." (Doc. No. 97 ¶ 283.)

6 This is one allegation that Defendants have already contested. Lengthier discussion follows below.

7 Prior to the 2009 amendments to the FCA, the relevant provision was § 3729(a)(1), which applies to "any person who ... knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval."

8 Though the parties both cite it, the *Fontanive* case is curiously unavailable through the usual electronic databases and search engines. A copy of the slip opinion is on file with the Court.

9 Relatedly, Relator alleges that Omnicare's Chief Operating Officer "ordered her to cease all collection efforts at Five Star" because, "despite the size of Five Star's debt ... Omnicare needed to 'tread lightly' because Omnicare was attempting to purchase pharmacies from Five Star." (Doc. No. 97 ¶ 324.)

10 Relator alleges that this exchange continued with Relator exclaiming "But that's inducement!" and Richow agreeing and telling her that the Executive Director of Pharmacy for the New York region "would be the 'first to go to prison' over such an arrangement." (Doc. No. 97 ¶ 313.)

11 There is not a black-and-white circuit split here, but there certainly exists more than one analytical approach. Whereas the Second Circuit has held that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid," *Mikes,* 274 F.3d at 700, the Tenth and D.C. Circuits have acknowledged that conditions contained within an underlying contract between a service provider and the Government can give rise to implied false certification liability, *Shaw v. AAA Eng'g & Drafting, Inc.,* 213 F.3d 519, 533 (10th Cir.2000); *see also Sci. Applications Int'l Corp.,* 626 F.3d at 1269. What is more, the First Circuit has apparently declined to adopt the term "implied false certification," but has embraced the Tenth/D.C. Circuit rule.

*See United States ex rel. Hutcheson v. Blackstone Med., Inc.,* 647 F.3d 377, 393 (1st Cir.2011). In fact, the *Hutcheson* court reached that conclusion in the course of holding that the Medicare "Provider Agreement is also sufficiently clear to establish that the claims submitted by *physicians* represented that the underlying transactions did not involve kickbacks to physicians prohibited by the AKS." *Id.* (alteration in original). Finally, the Fourth Circuit has yet to rule the implied certification theory in or out, but has discussed it with some skepticism. *See United States ex rel. Herrera v. Danka Ofice Imaging Co.,* 91 F. App'x 862, 864 (4th Cir.2004).

12 It is true that Relator does not allege who signed each and every certification document, but that is less important here, where the scheme has pervaded the organization and occurred over a lengthy period of time.

13 On the other hand, as the First Circuit has noted, the language of the cost reports "makes it abundantly clear that AKS compliance is a precondition of Medicare payment." *United States ex rel. Hutcheson v. Blackstone Med., Inc.,* 647 F.3d 377, 393 (1st Cir.2011).

14 The Court does not reach the Government's more adventuresome contention, that "[w]hen the government has made clear that payment is conditioned upon certain requirements, a claim for goods or services that do[es] not comply with those criteria is 'false' regardless of what certifications are made in conjunction with that claim." (Doc. No. 135 at 13.)

15 As to her retaliation claim, Relator is more accurately considered a Plaintiff, as she is pressing it on her own behalf, but for the sake of consistency, the Court will continue to use "Relator."

16 And moreover, it cannot necessarily be said that Relator did not try to stop fraud. By seeking to collect from Five Star (Doc. No. 97 ¶ 311), Relator essentially tried to prevent kickbacks from being paid, which would in turn lead to future claims not being false.

17 The Court notes that, per the TAC, on the Sunday evening that Relator returned from her August 2008 vacation and could not access her computer, Richow told her that he did not know why she was having such problems. (Doc. No. 97 ¶ 330.) That, in turn, could suggest that he did not know she was going to be terminated the next day and thus had not spoken to any other Omnicare executives about Relator's concerns. If all of that were true, perhaps Relator's employer could not be said to have had knowledge of her protected activity. But it is not for today to figure out which of two alternative scenarios played out. Relator's allegations rise to the level of plausibility necessary for her suit may proceed.

18 The new version of the statute subjects to liability an individual who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)." 31 U.S.C. § 3729(a)(1)(C).

19 (Doc. No. 137 at 41.)

20 Section 3729(a)(7) has since been recodified as § 3729(a)(1) (G).

21 The Court dismisses all § 3729(a)(7) claims: those premised upon false cost reports and those based on violations of Omnicare's Corporate Integrity Agreement. Because, at least as a factual matter, the latter claims are distinguishable from those at issue in *Thomas, Taylor,* and *HCA Health Services,* Relator should file a motion pursuant to Federal Rule of Civil Procedure 59 if she believes they also differ in a legally relevant manner. Briefing already on file is not sufficient to answer the question.

22 Indeed, the case relied upon by the *Edwards* court held that "[f]ailure to comply with this condition precedent is grounds for dismissing New York state-law claims in federal court" and did not concern itself with failure to plead compliance. *Cantave v. New York City Police Officers.* No. 09–CV–2226 (CBA)(LB), 2011 WL 1239895, at *12 (E.D.N.Y. Mar. 28, 2011).

23 Of course, should Defendants renew this argument, the Court would take a closer look at whether they are the proper parties to be making it.

24 Relator has conceded that Montana's Act is explicitly prospective (Doc. No. 137 at 50), and so no claims arising before Oct. 1, 2005 can be vindicated under the laws of that state.

25 Petitioners for a Writ of Habeas Corpus may be one obvious exception.

End of Document

# APPENDIX E

2016 WL 80000
United States District Court,
N.D. Texas, Dallas Division.

UNITED STATES of America ex rel. Kevin N. Colquitt, Plaintiff,
v.
ABBOTT LABS., et al., Defendants.

No. 3:06-CV-1769-M
|
Signed 01/07/2016

**Attorneys and Law Firms**

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**MEMORANDUM OPINION AND ORDER**

BARBARA M. G. LYNN, UNITED STATES DISTRICT JUDGE

***1** Before the Court are a Motion for Partial Summary Judgment [Docket Entry #440], filed by Relator Kevin N. Colquitt ("Relator"), and a Motion for Summary Judgment [Docket Entry #443], filed by Defendants Abbott Laboratories and Abbott Vascular Solutions, Inc. (together, "Abbott" or "Defendants"). For the reasons stated, both motions are DENIED.

I.

This is a *qui tam* action brought by Relator, a former employee of Guidant Corporation ("Guidant") and Guidant's successor-in-interest Abbott, for alleged violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"), in connection with claims for reimbursement of vascular stenting procedures involving Guidant-and Abbott-brand biliary stents submitted to Medicare between February 23, 2004 and June 21, 2006. *See* Mem. Opinions [Docket Entry ## 160, 313, & 434]. Because this case has been the subject of several prior opinions, *see id.*, the Court limits its discussion to the select legal and factual issues upon which the motions for summary judgment turn.

II.

As a preliminary matter, Relator has filed a Motion to Strike [Docket Entry # 459] and a Supplemental Motion to Strike [Docket Entry #495]. By his motions to strike, Relator seeks to exclude six categories of evidence relied upon by Defendants in their summary judgment motion and response, including: (1) undisclosed fact witnesses; (2) inadmissible hearsay evidence from fact witnesses through proposed expert testimony and reports; (3) opinion evidence from physicians solely designated as fact witnesses; (4) inadmissible expert testimony relying on the opinions of the physician fact witnesses; (5) evidence not timely disclosed in fact discovery; and (6) inadmissible hearsay evidence.[1] Relator's supplemental motion is further directed to striking an email exchange between Dr. Gary Dorfman and Dr. Katherine Krol, which occurred during the course of Dr. Krol's engagement as an expert in this case. Relator seeks to strike the email exchange and Krol's reliance on it because the document is (1) inadmissible hearsay, and (2) Dr. Dorfman is an undisclosed fact witness. The Court has not relied on any of this allegedly objectionable evidence in making its determination on the pending summary judgment motions. Accordingly, Relator's Motion to Strike and Supplemental Motion to Strike are DENIED as moot.

Relator also has filed a Motion to Exclude the testimony of Dr. Krol. [Docket Entry #488]. Dr. Krol, an interventional radiologist, has offered opinions on: (1) the correct Medicare codes for placement of biliary stents in the peripheral vasculature; (2) the propriety of Medicare reimbursement for use of biliary stents in peripheral vascular procedures; and (3) the appropriateness of off-label biliary stent use during the early to mid-2000s. Relator objects to, and moves to exclude, these opinions on grounds of reliability and relevancy. First, Relator argues Dr. Krol's opinions that Medicare contractors knew of and agreed to reimburse providers for peripheral vascular stenting procedures using unapproved biliary stents are not reliable because they are based on inadmissible hearsay from other physicians. Relator also contends that Dr. Krol's Medicare coverage and coding opinions are unreliable because they are based on alleged informal

 

conversations with CMS, local contractors, and FDA, not official policy statements from a relevant agency. Further, Relator contends that Dr. Krol's role as an advocate prevents her from offering objective testimony and that Dr. Krol's lay witness testimony should be excluded because she was not timely disclosed as a fact witness. Notwithstanding these objections, Relator frequently cites to Dr. Krol's testimony in support of his own summary judgment motion. The Court determines that it can resolve the pending motions without relying on Dr. Krol's expert opinions. Accordingly, it will not consider Dr. Krol's opinions as evidence on summary judgment. The Court reserves Relator's *Daubert* challenges for determination either at trial or at a pretrial hearing for that purpose. *See Nielsen v. Alcon, Inc.*, 2011 WL 4529762 at *5 (N.D. Tex. Sept. 2, 2011), *rec. adopted*, 2011 WL 4529674 (N.D. Tex. Sept. 30, 2011) (recognizing that a trial setting normally provides the best environment for resolving *Daubert* challenges).

III.

***2** Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. A dispute as to a material fact is genuine, if the evidence is sufficient to permit a reasonable factfinder to return a verdict for the nonmoving party. *Crowe v. Henry*, 115 F.3d 294, 296 (5th Cir. 1997). A fact is material if its resolution could affect the outcome of the action. *Weeks Marine, Inc. v. Fireman's Fund Ins. Co.*, 340 F.3d 233, 235 (5th Cir. 2003). The substantive law determines which facts are material. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

A party seeking summary judgment who does not have the burden of proof at trial, like Defendants here, need only point to the absence of admissible evidence to support the nonmovant's claim. *See Duffy v. Leading Edge Prods., Inc.*, 44 F.3d 308, 312 (5th Cir. 1995). Once the movant meets its initial burden, the burden shifts to the nonmoving party to produce evidence or designate specific facts in the record showing the existence of a genuine issue for trial. *See Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). By contrast, a movant who bears the burden of proof at trial, such as Relator, must establish "beyond peradventure *all* of the essential elements of the claim or defense to warrant judgment in his favor." *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1194 (5th Cir. 1986) (emphasis in original). The "beyond peradventure" standard is a "heavy" burden. *See Carolina Cas. Ins. Co. v. Sowell*, 603 F. Supp. 2d 914, 923–24 (N.D. Tex. 2009).

IV.

The FCA imposes liability on any person who (1) "knowingly presents, or causes to be presented, to the United States Government a false or fraudulent claim for payment or approval" or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. §§ 3729(a)(1)(A), (B). In this case, Relator proceeds on two theories of liability, asserting both a "false presentment" claim and a "false statement" claim. Relator's false presentment claim is based on his argument that Defendants' biliary stents were not eligible for Medicare reimbursement. His false statement claim is related to the use of billing codes that allegedly misrepresented the nature of the stent used in the procedure for which reimbursement was sought.

Defendants move for summary judgment on three grounds: (1) Relator cannot establish the existence of any false claims; (2) Relator cannot establish Defendants' scienter; and (3) Relator cannot show that Defendants caused any provider to submit claims for reimbursement for vascular procedures using biliary stents. Relator also moves for partial summary judgment with respect to three elements of his FCA claim —falsity, materiality, and scienter—and argues that the case should proceed to trial on the issues of causation and damages.

a.

The threshold question in this case is whether claims for Medicare reimbursement of vascular stenting procedures involving Defendants' biliary stents constitute false claims under the FCA. Relator initially contends that the claims at issue are false because they are categorically ineligible for Medicare coverage. According to Relator, Medicare only pays claims for items and services that qualify as "reasonable and necessary," and an item or service must be affirmatively determined by the Food and Drug Administration ("FDA") to be safe and effective in order to qualify as reasonable and necessary. Relator argues that the FDA had not determined the safety and effectiveness of Defendants' biliary stents for use in the vascular system, and therefore the stents were not eligible for Medicare coverage. Because Medicare claims

for expenses that are not covered and are ineligible for payment are false, as a matter of law, Relator asserts that he is entitled to summary judgment affirmatively establishing the primary element of his FCA claim. Defendants dispute Relator's assertions and argue that the claims at issue were eligible for reimbursement, and, in fact, properly reimbursed by the private insurance companies that were charged with the task of processing Medicare claims.

***3** The Center for Medicare and Medicaid Services ("CMS") oversees the Medicare program at a national level, but it does not process individual claims submitted by health care providers for reimbursement. Instead, CMS contracts with private insurance companies to act as its agents in reviewing and processing Medicare claims. *See* Rel. App. at 497, ¶ 10. CMS has the authority to make Medicare coverage eligibility determinations for medical devices on a nationwide basis. When it makes a rule regarding the scope of coverage for a particular device, CMS issues a National Coverage Decision ("NCD"). *See* 42 C.F.R. § 405.1060(a)(1) ("An NCD is a determination...of whether a particular item or service is covered nationally under Medicare."). An NCD is binding on all private Medicare contractors. *Id.*, § 405.1060(a)(4), (b)(1). The private contractors are also bound by the terms of the Medicare statute in making reimbursement decisions. Among other things, the statute provides that "no payment may be made...for any expenses incurred for items...[which] are not reasonable and necessary for the diagnosis of illness or injury...." 42 U.S.C. § 1395y(a)(1)(A). The private Medicare contractors determine which items are reasonable and necessary for purposes of coverage under the statute. *See* Rel. App. at 500, ¶ 15. If there is no NCD in place, Medicare contractors can issue Local Coverage Determinations ("LCDs") that address the reimbursement eligibility of certain procedures. *Id.*, ¶ 16. LCDs are binding only in the local areas for which the particular contractor has authority. 42 U.S.C. § 1395ff(f)(2)(B).

In this case, it is undisputed that there was no NCD in effect between 2004 and 2006 that addressed whether claims for vascular stenting procedures using biliary stents were covered by Medicare and eligible for reimbursement. *See* Rel. App. 505. Despite the lack of a nationwide rule, Relator argues that Defendants' stents are categorically ineligible for Medicare coverage because they cannot satisfy the statute's reasonable and necessary requirement. Medicare contractors look to the Medicare Program Integrity Manual ("MPIM"), promulgated by the Secretary of Health and Human Services, for guidance in applying the "reasonable and necessary" standard. *See* Rel. App. 414-51. The MPIM directs that a device will be considered "reasonable and necessary" if the contractor determines that the item is "safe and effective," "not experimental or investigational," and "appropriate" in terms of accepted medical practice and the patient's medical need. *Id.* at 424. Relator contends that the FDA's determinations of safety and effectiveness are "dispositive" for purposes of determining whether a product satisfies the Medicare statute's reasonable and necessary requirement. In this case, the FDA determined that Defendants' biliary stents "had not been established" to be safe and effective when used in the vascular system, and even required the stents to carry a label to that effect. *See* Rel. App. at 1503-1150. Therefore, Relator argues, Defendants' biliary stents were ineligible for Medicare coverage on a nationwide basis.

Relator's argument oversimplifies the eligibility question. An FDA determination regarding the safety and effectiveness of a device is not a substitute for CMS review of whether the device is eligible for coverage. CMS and its contractors determine when a device is reasonable and necessary, and thus eligible for coverage, under the Medicare statute. *See* 68 Fed. Reg. 55,634 (Sept. 26, 2003). The FDA conducts premarket review of products under different statutory standards. *Id.* A device may be approved or cleared by the FDA and still not be eligible for Medicare coverage. *See id.* Further, lack of FDA approval or clearance for a specific use does not categorically disqualify a device from Medicare coverage. *See id.* Medicare reimbursement for off-label uses is permissible in some instances. *United States ex rel. Modglin v. DJO Global Inc.*, 48 F. Supp. 3d 1362, 1392 (C.D. Cal. 2014); *see also United States ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745, 754 (S.D. Tex. 2010) (observing that Medicare does not impose an absolute ban on coverage for off-label use of drugs and devices); *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F.Supp.2d 310, 347 (D. Mass. 2011) (same); *Strom ex rel. United States v. Scios, Inc.*, 676 F.Supp.2d 884, 886 (N.D. Cal. 2009) (same). Relator has not established "beyond peradventure" that all claims for Medicare reimbursement of vascular stenting procedures involving Defendants' biliary stents are false claims under the FCA.

***4** In the absence of an NCD governing the vascular stenting procedures at issue in this case, local Medicare contractors had discretion to make coverage determinations regarding the procedures. *See* Rel. App. at 505, ¶ 29. Between 2004 and 2006, local contractors with responsibility for roughly half of the United States issued at least fifty different LCDs addressing non-coronary vascular stenting. *See* Rel. App. at

1501-2293. These LCDs expressly recognized that coverage was allowable for procedures involving the off-label use of a stenting device in various circumstances. To determine whether procedures using Defendants' biliary stents were covered requires a fact-intensive analysis of the specific terms of each LCD. For example, New Jersey's Part B Medicare carrier had an LCD in place until January 3, 2005 that limited coverage to stents "used for the FDA-approved indication." Given this limitation, Defendants concede that Medicare claims for vascular procedures using their biliary stents were not eligible for reimbursement. *See* Def. MSJ Br. at 30; Rel. App. at 537, ¶ 47. Therefore, a claim submitted to New Jersey's Part B Medicare carrier while this LCD was in effect would constitute a false claim. Defendants are not entitled to summary judgment on Relator's FCA claims that involve requests for Medicare reimbursement governed by the New Jersey plan. This analysis must be repeated for each LCD pursuant to which claims for reimbursement were processed. The parties have not attempted to perform such an analysis at this juncture in the litigation, and the Court declines to do so *sua sponte*. *See Franklin*, 2003 WL 22048255, at *3.

Relator contends that he can establish falsity as a matter of law without any LCD-specific analysis because all of the LCDs "uniformly required the use of an FDA approved vascular stent," and Defendants' stents were neither "vascular stents" nor "FDA approved." The Court rejects this attempt to circumvent the necessary analysis. The LCDs do not "uniformly require" any particular element; instead, the LCDs require different combinations of distinct conditions. The Court further observes that several of the LCDs use the term "vascular stent" in a manner that does not necessarily preclude coverage of "biliary stents." The LCDs in effect in Region X, an area that covers several northwestern states, describe the devices that may be used in covered procedures as follows:

> A stent is defined as a tubular-shaped device used to provide post dilitation support for narrowed or obstructed structures (e.g., vessels, biliary tract, and esophagus) to induce or maintain patency in an anatomic site. *Vascular stents are used to maintain patency in arteries and veins usually at the site of stenotic lesions*. Vascular stents are typically made of metallic interlocking threads that compress to fit near the tip of a catheter. They are deployed with the used of radiological guidance into a vessel with either self-expanding capabilities or with the use of a balloon catheter. Once deployed, the device remains in the vessel to provide support and patency of the narrowed vessel.

Def. App. at 2442; *see also id.* at 2451, 2460, 2469, 2478. Thus, at least some of the applicable LCDs define "vascular stents" with respect to their function, or use in the arteries or veins. Such a definition does not automatically prohibit a "biliary stent" from functioning as a vascular stent.

Relator argues that Defendants' stents are ineligible for coverage because a "majority" of the LCDs provide that "[c]overage for above indications for non-coronary vascular stents depends on the use of an *FDA approved* stent" and "[s]tent placement is covered by Medicare only when an *FDA approved* stent is … used." Rel. App. at 1942 (emphasis added); *see also id.,* at 1501-2076. The Court has previously determined that this language creates a plausible basis to infer that the LCDs containing this limitation only provide coverage for off-label uses of Class III vascular stents that have received approval through the premarket approval process. *United States ex rel. Colquitt v. Abbott Labs*., 864 F. Supp. 2d 499, 531 (N.D. Tex. 2012) ("*Colquitt I*"). However, this inference, without more, is insufficient to satisfy Relator's burden on his motion for summary judgment.

Relator points to testimony by Defendants' experts to support his interpretation of the LCDs, but the experts' testimony is neither entirely clear nor unequivocal. Relator also ignores Dr. William Mangold's expert report—that he included in the summary judgment record— which explains that Medicare contractors use the term "FDA approved" to refer to devices merely "cleared" through the FDA's 510(k) process, like Defendants' biliary stents. The summary judgment record establishes that a genuine dispute exists as to whether LCDs that limit coverage to procedures involving "FDA approved" devices encompasses Defendants' biliary stents.[2]

***5** Local contractors with responsibility for the rest of the United States did not issue LCDs for non-coronary vascular stenting. Relator asserts that "[i]n the absence of locally approved coverage, off-label uses are considered not reasonable and necessary." Relator's sole support for this assertion is the "Krubsack letter" and Dr. Krol's testimony explaining the letter, which he objected to and moved to strike. The Court has determined not to consider this evidence for purposes of the summary judgment motions. Without this or any other evidence, Relator cannot satisfy his summary judgment burden.

b.

Next, Relator argues that claims to Medicare involving Defendants' biliary stents were false because the claims were assigned billing codes that misrepresented the nature of the stent used in the procedure. Claims are submitted to Medicare using a 5-digit billing code based on the Current Procedural Terminology Manual ("CPT code"), promulgated by the American Medical Association. Each CPT code corresponds to a specific medical service, and the amount Medicare pays for a service is based on the CPT code. CPT codes 37205 and 37206 correspond to the placement of an *intravascular* stent in a non-coronary vessel. Defendants allegedly instructed their customers and health care providers to use CPT codes 37205 and 37206 to bill Medicare for vascular stent procedures using *biliary* stents, rather than a code for an unlisted procedure, like CPT code 37799 for "unlisted procedure, vascular surgery," or a code with a GZ modifier, which would convey additional information about a claim where non-covered items were used.

In support of his argument, Relator points to testimony by Defendants' coding experts that concede CPT code 37205 does not inform the Medicare contractor that an FDA cleared biliary stent may have been used in the intravascular stenting procedure—or provide any information whatsoever regarding the nature of the stent involved. *See* Rel. App. at 3692. Defendants respond that their experts also testify that CPT codes 37205 and 37206 were unquestionably the correct codes for health care providers to use when submitting claims to Medicare for reimbursement of vascular stenting procedures using their biliary stents. See Def. App. at 1670, 1675-81. Medicare reimbursement procedures and coding requirements are proper subjects of expert testimony. *United States v. White*, 492 F.3d 380, 403-04 (6th Cir. 2007). Here, the expert testimony regarding the propriety of using CPT codes 37205 and 37206 on claims involving Defendants' stents is in conflict and raises a genuine dispute of material fact that makes summary judgment inappropriate.

c.

Relator also moves for summary judgment on the issue of materiality with respect to his false statement claims. Liability under the FCA requires that the falsity be material to the claim. In the Fifth Circuit, "a false statement is material if it has a 'natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed.' " *United States ex rel. Longhi v. United States*, 575 F.3d 458, 468 (5th Cir. 2009) (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)).

According to Relator, the CPT codes are material because a "clean" 37205 or 37206 code, without a GZ modifier, resulted in automatic payment. Defendant does not dispute this assertion, but points out that Relator's own expert testified that use of a GZ modifier or even the 37799 code would not necessarily result in claim denial. Def. App. 2705-06. Relator has not established materiality "beyond peradventure," and his motion for summary judgment as to this element is denied.

d.

***6** Both parties move for summary judgment on scienter. The scienter requirement comes from the FCA's requirement that the person to be held liable must have acted "knowingly." For purposes of the FCA, the term "knowingly" means that a person (1) has actual knowledge of the truth or falsity of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required. *Id.* The state of knowledge is usually a factual inquiry. However, summary judgment may be granted where there is no evidence of the requisite scienter. *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008).

Defendants argue that Medicare coverage of biliary stents was "arcane and confusing" and that, as a matter of law, they did not have scienter because they objectively and reasonably believed that Medicare properly reimbursed vascular stenting procedures using biliary stents between 2004 and 2006. Defendants have produced evidence that they believed such procedures were reimbursable and that their belief was reasonable because it was shared by numerous providers, medical societies, and Medicare contractors. Relator, on the other hand, has pointed to evidence, which if believed, indicates Defendants had a far-reaching scheme to unlawfully benefit from an off-label use of their products and never had a good faith belief that their stents were eligible for Medicare reimbursement. Circumstantial evidence can support a scienter inference. *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 287 (5th Cir. 2006).

Relator also has adduced evidence that Defendants avoided making any inquiries that would confirm whether claims for vascular procedures using its stents were eligible for

reimbursement. Rel. App. 3043, 3063, 3067, 3040-50. The evaluation of this evidence, including the testimony of Guidant's Director of Reimbursement Linda Dickes, requires credibility determinations. Whether Defendants objectively and reasonably believed that Medicare could properly reimburse vascular stenting procedures using biliary stents is a genuinely disputed fact question that is not appropriate for summary judgment.

e.

Finally, Defendants move for summary judgment on causation. The FCA does not define the phrase "cause to be presented," *see* 31 U.S.C. § 3729, *et seq.,* and the Fifth Circuit has not delineated a specific causation standard applicable to FCA claims. The Court thus finds it appropriate to apply common-law tort concepts of proximate causation to determine whether there is a sufficient nexus between the Defendants' conduct and the ultimate presentation of the allegedly false claim. This approach is consistent with that of well-reasoned decisions by other courts. *See, e.g., United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006); *Franklin*, 2003 WL 22048255, at *5. Accordingly, Defendants' conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of Defendants' conduct. *Franklin*, 2003 WL 22048255, at *5.

The Court determines that Relator has identified enough evidence to raise a genuine fact dispute as to whether Defendants' conduct was a substantial factor in causing the presentment of Medicare claims for reimbursement. In particular, Relator has produced evidence that Defendants employed a multitude of sales representatives to market and sell biliary stents to cardiologists, vascular surgeons, and interventional radiologists performing vascular procedures, *see, e.g.,* Rel. App. at 5514, 5536, and that, in connection with their sales efforts, Defendants offered training and advice on Medicare reimbursement procedures, *see id.* at 3906-07. Relator's evidence also raises at least the inference that Defendants' customers heeded the sales representatives' advice and submitted claims to Medicare for reimbursement of procedures using Defendants' stents. Relator has produced a November 2001 email from Jim Neupert, Guidant's Vice President of Marketing, that a health care provider used a Medicare coding guide provided by a Guidant employee in connection with a successful claim for reimbursement. Rel. App. at 3873-74. Although the Neupert email is outside the relevant time period for this action, it is undisputed that Defendants engaged in similar marketing activities— and that Defendants' customers continued to submit claims for Medicare reimbursement— between February 23, 2004 and June 21, 2006.

***7** Defendants dispute whether any provider ever used or relied on information or advice provided by Guidant or Abbott in connection with the submission of reimbursement claims to Medicare. Among other things, Defendants note that numerous independent sources instructed health care providers on the proper submission of claims to Medicare for reimbursement of vascular procedures using biliary stents. *See, e.g.,* Def. App. at 1676-79. They further note that Relator's own expert, Wendy Britton Knau, testified at her deposition that she has no knowledge of any person who relied on Defendants' coding guidelines during the period at issue to determine how to code a procedure where a biliary stent was used in the peripheral vasculature. *See* Def. App. at 196. The evidence, viewed as a whole, raises a fact question on the substantial factor element, and the Court will leave to the jury the task of making credibility determinations and weighing conflicting evidence.[3]

The summary judgment evidence is also sufficient to raise a genuine fact dispute as to whether it was reasonably foreseeable that Defendants' conduct would lead to the submission of false claims for reimbursement. Viewing the evidence in the light most favorable to Relator, as the Court must do in considering Defendants' summary judgment motion, a jury could find that a reasonably foreseeable result of Defendants' efforts to market and sell biliary stents to health care professionals for use in vascular procedures would be the submission of Medicare claims for reimbursement of those procedures. Defendants' efforts specifically included training and advice on Medicare reimbursement.

To the extent Defendants contend there is no fact question on causation because there is no evidence that they completed, or otherwise controlled the content of a claim for Medicare reimbursement, the lack of such evidence is not necessarily fatal to Relator's claim. The law does not require direct involvement in the submission process to establish liability. Rather, the law merely demands more than mere passive acquiescence in the presentation of the claim and "some sort

of affirmative act" that causes or assists the presentation of a false claim. *See Sikkenga*, 472 F.3d 715; *see also United States v. Mackby*, 261 F.3d 821, 824–26, 828 (9th Cir. 2001) (affirming FCA liability of owner/managing director of physical-therapy clinic who instructed the clinic's billing company to use an improper code on Medicare reimbursement claim forms; stating, "[A] person need not be the one who actually submitted the claim forms in order to be liable"). The evidence here is sufficient to raise a genuine dispute as to whether Defendants engaged in an affirmative act that caused the presentation of a false claim. Accordingly, Defendants' motion for summary judgment on the issue of causation is denied.

V.

For the reasons stated, Relator's Motion to Strike [Docket Entry # 459] and Supplemental Motion to Strike [Docket Entry #495] are DENIED as moot.

Defendants' Motion for Summary Judgment [Docket Entry #443] and Relator's Motion for Partial Summary Judgment [Docket Entry #440] are DENIED.

SO ORDERED.

**All Citations**

Not Reported in Fed. Supp., 2016 WL 80000, Med & Med GD (CCH) P 305,511

Footnotes

1 Relator identifies the objectionable evidence as Def. App. 3-18, 78-101, 113-31, 174-88, 198-261, 266-72, 361-591, 1236-41, 1269-1271, 1280-85, 1297-98, 1312, 1398-1478, 1498, 1505, 1514, 1530-34, 1709-10, 1711-13, 1734-36, 2033-40, 2041-52, 2053-69, 2099-2101, 2102-09, 2107-09, and 2818-21.

2 In addition to conditioning coverage on the use of an "FDA approved" stent, a number of the LCDs also require that the use of the stent be "supported by the peer medical literature" or that the use "represent current standard practice in the medical community." Expert testimony is required to determine the import of the peer medical literature and the standard practice in the medical community. The expert testimony on these subjects is in conflict, and much of the testimony has been challenged on *Daubert* and other grounds. The Court is not now taking any position on the admissibility of the expert testimony.

3 Defendants identify other evidence in support of their contention that providers did not use their coding guidelines to decide how to code the procedures at issue in this case, including testimony by several doctors who coded claims as part of their practice. *See, e.g.,* Def. App. 100, 1237, 1242, 1270-71, 1330, 1451. However, Relator has objected to this evidence and moved to strike it from the summary judgment record, and the Court does not rely on it to support its determination of the pending motions.

# APPENDIX F

2021 WL 742887
Only the Westlaw citation is currently available.
United States District Court,
S.D. Texas, Houston Division.

Margaret VOORHEES, Plaintiff.

v.

KELSEY-SEYBOLD CLINIC, P.A., Defendant.

Civil Action No. 4:18-CV-03748
|
Signed 01/29/2021

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**MEMORANDUM AND RECOMMENDATION**

ANDREW M. EDISON, UNITED STATES MAGISTRATE JUDGE

***1** Plaintiff Margaret Voorhees ("Voorhees") brings this *qui tam* lawsuit against Defendant Kelsey-Seybold Clinic, P.A. ("Kelsey-Seybold"), alleging that the health provider fraudulently billed federal healthcare programs for services that did not meet Medicare coverage requirements. Now before me is Defendant's Motion to Dismiss Relator's Second Amended Complaint. Relying on Federal Rules of Civil Procedure 8(a), 9(b), 12(b)(1), and 12(b)(6), Kelsey-Seybold asks me to throw out this entire lawsuit. After reviewing the motion, the response, the reply, the operative complaint, and the applicable legal authorities, I **RECOMMEND** that the motion be **GRANTED** in part and **DENIED** in part.

**THE FALSE CLAIMS ACT**

"First passed at the behest of President Lincoln in 1863 to stem widespread fraud by private Union Army suppliers in Civil War defense contracts," the False Claims Act ("FCA") "is intended to protect the Treasury against the hungry and unscrupulous host that encompasses it on every side." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 184 (5th Cir. 2009) (cleaned up). To that end, the FCA imposes liability on "any person" who, among other things, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States government, or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B).

The FCA permits a private person, known as a "relator," to bring an action in the name of the United States for a violation of the FCA. *See id.* § 3730(b)(1). Such lawsuits are commonly referred to as *qui tam* suits. "*Qui tam* is short for the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, which means 'who pursues this action on our Lord the King's behalf as well as his own.' " *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 768 n.1 (2000). Relators have standing to sue in *qui tam* actions because "a *qui tam* relator is, in effect, suing as a *partial* assignee of the United States['s]" claim for damages. *Id.* at 773 n.4.

The FCA encourages private citizens to report fraud by promising them a percentage of any eventual recovery obtained through a final judgment or settlement. *See* 31 U.S.C. § 3730(d). All told, *qui tam* suits have netted the government more than $60 billion in recoveries since 1986 and are averaging several billion dollars a year in recent years. *See* JOHN T. BOESE, *Civil False Claims and Qui Tam Actions* § 3 (5th ed. 2020), Westlaw 2015 WL 5620018.

"After the relator has filed suit, the action is sealed for sixty days while the government decides whether to intervene." *United States ex rel. Jaison v. McKesson Corp.*, 649 F.3d 322, 325 n.3 (5th Cir. 2011) (citing 31 U.S.C. § 3730(b)(2)). "If the government chooses not to intervene, the relator may proceed independently." *Id.* (citing 31 U.S.C. § 3730(e)(4)(B)). If the government intervenes and takes over the action, the relator may receive 15 to 25 percent of the proceeds of the action or settlement. 31 U.S.C. § 3730(d)(1). If the government declines to intervene, the relator may receive 25 to 30 percent. *Id.* § 3730(d)(2).

**FACTUAL BACKGROUND**

***2** Accepting the allegations in the Second Amended Complaint as true and construing them in the light most favorable to Voorhees, the pending lawsuit sets forth a

 

relatively simple, yet devious, plot to defraud the federal government. Kelsey-Seybold provides healthcare services in the Greater Houston area through primary care physicians and specialists located at 20 separate facilities. Voorhees began working for Kelsey-Seybold on January 23, 2017, as a billing specialist. Soon after her employment began, Voorhees discovered that Kelsey-Seybold "billed federal healthcare programs for services that did not meet Medicare coverage requirements" and "also padded its bills so as to include services that did not occur." Dkt. 20 at 3–4. In particular, Voorhees claims that Kelsey-Seybold improperly coded patients as consults, rather than new patients.

"A new patient code solely applies to a patient who has not received professional service from that physician or a physician in the same specialty or practice within a specified time." *Id.* at 6. Meanwhile, "[a] consultation code solely applies to a physician whose opinion regarding an evaluation was either requested by another physician or from another source that referred the patient to the physician." *Id.* The reason coding is significant, according to the live complaint, is that labeling a patient as a consult, as opposed to a new patient, results in larger (and unwarranted) payments due Kelsey-Seybold from the federal government. According to Voorhees, "Kelsey-Seybold engaged in [this] scheme to bill Medicare at an incorrect code without regard to patients' actual conditions or needs, or the costs to Medicare." *Id.* at 5.

Voorhees claims that she discovered this ruse and immediately brought the issue to the attention of her supervisors at Kelsey-Seybold. The operative complaint recounts several occasions in which she raised the improper coding with others at Kelsey-Seybold, but her efforts were reportedly rebuffed at each and every turn. When her superiors at Kelsey-Seybold continuously refused to do the right thing and code properly, Voorhees says she contacted the Office of Inspector General to air her grievances about the company's illegal and unethical billing practices. "Despite [Voorhees's] best attempts to get Kelsey-Seybold to stop its practices, Kelsey-Seybold physicians continued to code their visits with patients inappropriately costing Medicare thousands of dollars." *Id.* at 4.

As a result of the conduct described above, Voorhees alleges that Kelsey-Seybold violated the FCA by (1) knowingly presenting a false claim for payment in violation of 31 U.S.C. § 3729(a)(1)(A); and (2) knowingly making or using a false record material to a false claim. *See id.* § 3729(a)(1)(B). Voorhees also advances an independent state law claim for unjust enrichment.[1]

## LEGAL STANDARDS

### A. Rule 12(b)(1)

A court must dismiss a suit for lack of subject matter jurisdiction under Rule 12(b)(1) where it lacks the statutory or constitutional power to adjudicate the case. *See Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). Subject matter jurisdiction fails if the plaintiff lacks Article III standing. *See Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 541–42 (1986). Therefore, when a plaintiff lacks standing to sue in federal court, it is appropriate to dismiss the action pursuant to Rule 12(b)(1) for want of subject matter jurisdiction. *See Chair King, Inc. v. Hous. Cellular Corp.*, 131 F.3d 507, 509 (5th Cir. 1997).

### B. Rule 12(b)(6)

***3** A pleading in a civil action must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 12(b)(6) provides that a defendant is entitled to dismissal when the plaintiff fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (cleaned up). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

In reviewing a Rule 12(b)(6) motion, I must "accept[ ] all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *See Alexander v. AmeriPro Funding, Inc.*, 848 F.3d 698, 701 (5th Cir. 2017) (quotation omitted). Because a complaint must be liberally construed in favor of the plaintiff, "a motion to dismiss under Rule 12(b)(6) is generally viewed with disfavor and is rarely granted." *See Harrington v. State Farm Fire & Cas. Co.*, 563 F.3d 141, 147 (5th Cir. 2009) (cleaned up).

**C. Rule 9(b)**

Because FCA claims involve allegations of fraud, they must comply with the heightened pleading requirements of Rule 9(b). *See Grubbs*, 565 F.3d at 185. That rule requires a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). More specifically, Rule 9(b) requires that a complaint detail "the who, what, when, and where before access to the discovery process is granted." *Hart v. Bayer Corp.*, 199 F.3d 239, 247 n.6 (5th Cir. 2000) (cleaned up). The Fifth Circuit has mandated that Rule 9(b)'s heightened standard for pleading is to be applied "with bite and without apology." *Grubbs*, 565 F.3d at 185 (quotation omitted). At a bare minimum, a FCA plaintiff must allege " 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.' " *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 240 (5th Cir. 2020) (*quoting Grubbs*, 565 F.3d at 185). The failure of a plaintiff to plead in compliance with Rule 9(b) is considered a failure to state a claim under Rule 12(b)(6). *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 (5th Cir. 1997).

**ANALYSIS**

**A. The Fca Claims**

To properly set forth a FCA claim, Voorhees must plead the following four elements: (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)." *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467 (5th Cir. 2009) (quotation omitted). Because, as already noted, "the linchpin of an FCA claim is a false claim," a plaintiff alleging a violation of the FCA must satisfy the heightened Rule 9(b) pleading standard. *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008). This requires Voorhees to identify "the time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby." *Id.* (cleaned up).

Kelsey-Seybold argues that the Second Amended Complaint fails to meet the Rule 9(b) pleading standard in two main respects. First, Kelsey-Seybold claims the operative complaint "fails to make particular allegations of fraud at the level of any individual transaction with the government." Dkt. 21 at 17. Second, Kelsey-Seybold avers that the Second Amended Complaint "fails to provide the particular details of a scheme to submit false claims." *Id.* at 19 (quotation omitted). Neither argument is persuasive.

***4** As to the first argument, Kelsey-Seybold claims that there are no direct allegations that it submitted any false claims to the federal government, and no factual basis for the contention that Kelsey-Seybold improperly submitted claims for payment by coding visits as consults, as opposed to new patients. Candidly, I am a tad puzzled by this line of reasoning. Based on my reading of the Second Amended Complaint, there are a litany of allegations that Kelsey-Seybold submitted claims to the federal government for payment. *See* Dkt. 20 at 3 (Kelsey-Seybold "bills Medicare on behalf of its physicians."); *id.* ("Kelsey-Seybold billed federal healthcare programs for services that did not meet Medicare coverage requirements."); *id.* at 4 ("Kelsey-Seybold knew or should have known that these services were incorrectly billed under the Medicare benefits it billed for."). Similarly, the Second Amended Complaint is replete with detailed allegations that Kelsey-Seybold improperly coded visits as consults when the patients were actual new patients. *See id.* ("Billing patients inappropriately as consults rather than as new patients costs Medicare more."); *id.* at 5 ("The illegal practice of billing patients to Medicare as consults rather than new patients occurred during Relator's entire Kelsey-Seybold employment."); *id.* at 8 (Kelsey-Seybold "knowingly presented ... claims for payment to Medicare and Medicaid for billing new patients as consults, despite Relator's best efforts to warn [Kelsey-Seybold] to cease such practices.").

Rule 9(b) presents a high, but not insurmountable, standard. This standard requires Voorhees to plead "reliable indications of fraud and to plead a level of detail that demonstrates that an alleged scheme likely resulted in bills submitted for government payment." *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 (5th Cir. 2013). I think the Second Amended Complaint easily passes this test. Voorhees alleges that her job as a billing specialist gave her a front row seat to Kelsey-Seybold's billing practices. For the entire seven-month time period she worked at Kelsey-Seybold, from January 23, 2017 through November 21, 2017, Voorhees claims she witnessed first-hand "Kelsey-Seybold engag[ing] in a scheme to bill Medicare at an incorrect code without regard to patients' actual conditions or need, or the costs to Medicare." Dkt. 20 at 5. Boiled down to its essence, Voorhees alleges that Kelsey-Seybold improperly

billed patients as consults when they were actually new patients. Because patients coded as consults are billed at a higher rate than patients coded as new patients, the natural effect of this purported mislabeling was that the federal government paid Kelsey-Seybold more money than it should have paid. Voorhees also contends that she tried to bring this issue to the attention of others at Kelsey-Seybold, including her supervisor (Marc Alcantara), a coder (Irma), a department head (Dr. Patel), an administrator (Mary Ann McBroom), and a senior coder (Maria Escobar). The live pleading describes in great detail Voorhees's protestations to Kelsey-Seybold management, and their refusal to revise their billing practices to address her concerns. This meets Rule 9(b)'s heightened pleading standard.

The one case Kelsey-Seybold highlights as "similar" to the allegations raised by Voorhees is *United States ex rel. Hebert v. Dizney*, 295 F. App'x 717 (5th Cir. 2008). Although *Dizney* also involved allegations of improper billing, the similarities stop there. Affirming the district court's dismissal, the Fifth Circuit noted that the live complaint simply lobbed together 21 corporate defendants and six individual defendants without any particularized allegations on what each defendant did wrong. *See id.* at 722. That is a far cry from this case's focused allegations that one corporate defendant operated a massive billing fraud.

Turning to Kelsey-Seybold's second main argument, the health provider argues that there is no factual support for the allegation that it engaged in a pattern or practice of submitting false claims. As discussed more fully above, I believe the allegations as they are spelled out in the Second Amended Complaint are sufficient to satisfy Rule 9(b)'s standards. Instead of broad and sweeping allegations devoid of substance, the Second Amended Complaint provides indicia of actual knowledge of FCA-violating fraud.

As I see it, Kelsey-Seybold's real complaint is that the lawsuit's allegations are simply untrue. According to Kelsey-Seybold, Medicare stopped recognizing consultation codes in 2010. As a result, Kelsey-Seybold claims it would be impossible to employ a scheme to submit claims for payment by coding visits as consults, rather than new patients. Additionally, while Voorhees's complaint is premised on the idea that Kelsey-Seybold received different sums from the government depending on how it coded patient visits, Kelsey-Seybold maintains that it was not reimbursed on a fee-for-service basis for most Medicare patients treated at its facilities since 2017. Kelsey-Seybold might be right. The allegations contained in the Second Amended Complaint might have no merit. But my job at this stage of the proceedings is not to conduct a deep dive into the merits of the claim. *See Twombly*, 550 U.S. at 556 ("A well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of [the alleged] facts is improbable, and that a recovery is very remote and unlikely.") (cleaned up). The issue at the motion to dismiss stage is not whether the plaintiff will ultimately prevail, but whether Voorhees is entitled to begin the discovery process and offer evidence to support her claims. Because I am obliged to "accept all well-pleaded facts as true, drawing all reasonable inferences in the nonmoving party's favor," I conclude that Voorhees has sufficiently stated an FCA claim as a matter of law. *See Benfield v. Magee*, 945 F.3d 333, 336 (5th Cir. 2019).

**B. Unjust Enrichment**

***5** In addition to bringing FCA claims, Voorhees asserts a common-law unjust enrichment claim. Kelsey-Seybold argues that the unjust enrichment claim must be dismissed under Rules 12(b)(1) and 12(b)(6) because Voorhees lacks standing to pursue the state law claim on behalf of the United States Government. I agree.

The law is well-settled. "A relator in a *qui tam* FCA action does not have standing to assert common law claims based upon injury sustained by the United States." *United States ex rel. Rockefeller v. Westinghouse Elec. Co.*, 274 F. Supp. 2d 10, 14 (D.D.C. 2003). *See also United States ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 451–52 (S.D.N.Y. 2001) (holding that a relator lacks standing to bring common-law claims of fraud, mistake of fact, and unjust enrichment); *United States ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000) (same). The reasoning behind this rule is simple and straightforward.

In *qui tam* suits, the real party in interest is the government. *See United States ex rel. Foulds v. Tex. Tech Univ.*, 171 F.3d 279, 289 (5th Cir. 1999). Congress has expressly authorized assignment of causes of action under § 3729. *See* 31 U.S.C. § 3730(b)(1) ("A person may bring a civil action for a violation of section 3729 for the person and for the United States Government."). That assignment, however, is limited by its express terms to violations of the FCA. Importantly, there is no assignment to individuals to bring *qui tam* claims under the common law or other statutes. *See United States ex rel. Ligai v. ETS-Lindgren Inc.*, No. H–112973, 2014 WL 4649885, at *15 (S.D. Tex. Sept. 16, 2014) (Although Congress specifically authorized "private litigants to sue for

damages for violations of § 3729, despite the fact that the only damaged party is the government, ... [t]here is no assignment to bring claims under the common law or other statutes."). Thus, a relator's standing extends only to the legal actions permitted by the FCA.

Voorhees argues that the Supreme Court's 2008 opinion in *Sprint Commc'ns. Co., L.P. v. APCC Servs. Inc.*, 554 U.S. 269 (2008) "made clear" that a relator has standing to assert common law claims, such as unjust enrichment, on behalf of the government. Dkt. 24 at 14. The obvious problem with this argument, as Kelsey-Seybold is quick to note, is that the *Sprint* decision "had absolutely nothing to do with whether an individual can pursue a common law claim on behalf of the federal government or with FCA claims at all." Dkt. 25 at 6. I have carefully reviewed *Sprint* and it provides no support for Voorhees's position. The *Sprint* case addressed whether third-party companies hired by pay-phone operators to collect compensation for coinless long-distance calls have standing to sue telecommunication companies over the amount of the fees. Nothing in the opinion remotely addresses the propriety of a relator bringing a common-law *qui tam* claim on behalf of the government. It is noteworthy that federal courts addressing the standing issue since *Sprint* have uniformly held that individual litigants cannot bring common law claims on behalf of the federal government. *See, e.g., United States v. Public Warehousing Co., K.S.C.*, 242 F. Supp. 3d 1351, 1361 (N.D. Ga. 2017); *Jacobs v. Bank of Am. Corp.*, No. 1:15-cv-24585, 2016 WL 11653744, at *8 (S.D. Fla. Dec. 20, 2016); *United States ex rel. Fortenberry v. Holloway Grp., Inc.*, 515 B.R. 827, 830 (W.D. Okla. 2014). I see no reason to forge a different path.

***6** In short, Voorhees lacks standing to file an unjust enrichment claim as a representative of the government. She has sustained no injury-in-fact, and has no Article III standing, but-for a partial assignment of the government's damages claim under the FCA. *See Vt. Agency of Nat. Res.*, 529 U.S. at 773.

### C. Leave To Amend

There is one more issue I need to address. Voorhees asks that she be permitted to amend her complaint if any part of Kelsey-Seybold's motion is granted.

As an initial matter, it is important to recognize that Voorhees has already been given three (that's right, three) opportunities to plead a proper claim. She filed an original complaint on October 10, 2018, an amended complaint on January 4, 2019, and a second amended complaint on July 7, 2020. Rule 15(a) provides that a plaintiff has the right to amend "once as a matter of course." Fed. R. Civ. P. 15(a)(1). "Once means once; the rule does not allow a right to amend after each amended complaint is filed." *C3PO Int'l, LTD. v. Dyncorp Int'l LLC*, 4:14-CV-564-A, 2016 WL 3417162, at *1 (N.D. Tex. Feb. 4, 2016).

In determining whether to grant Voorhees yet another chance to amend her complaint (that is, a fourth bite at the apple), I may consider a number of factors, including undue delay, bad faith or dilatory motive, repeated failures to cure pleading deficiencies, undue prejudice to the opposing party, and futility of amendment. *See Schiller v. Physicians Res. Grp., Inc.*, 342 F.3d 563, 566 (5th Cir. 2003). Curiously, Voorhees does not suggest that there are any additional facts she can allege at the present time to overcome the purely legal deficiency in her unjust enrichment claim. Instead, she asks me to, in effect, defer a ruling on the motion to dismiss so she can conduct discovery aimed at unearthing some factual basis for her unjust enrichment claim. *See* Dkt. 24 at 15 ("Many of the facts that Defendant seeks for purposes of clarification are properly obtained through discovery, which has yet to begin."). This is simply not permitted. *See Ambellu v. Re'ese Adbarat Debre Selma Kidist Mariam*, 406 F. Supp. 3d 72, 83 (D.D.C. 2019) (plaintiff's request to obtain discovery before responding to a motion to dismiss constituted an "end-run around well-established pleading standards"); *Felder v. WMATA*, 105 F. Supp. 3d 52, 59 (D.D.C. 2015) ("A plaintiff may not, however, use discovery to obtain the facts necessary to establish a claim."). Voorhees has already had three bites at the apple. Enough is enough. It would be futile to give her another opportunity to craft an unjust enrichment claim. She does not have standing to pursue an unjust enrichment claim and no amount of discovery will change that outcome. The request to amend the complaint is denied.

## CONCLUSION

***7** For the reasons stated above, I recommend that Defendant's Motion to Dismiss Relator's Second Amended Complaint (Dkt. 21) be **GRANTED** in part and **DENIED** in part. Specifically, I recommend that the FCA claims under 31 U.S.C. § 3729(a)(1)(A) and (B) remain alive and kicking, while the unjust enrichment and FCA retaliation claim be dismissed. I also reject Voorhees's request to file another amended complaint.

**All Citations**

Slip Copy, 2021 WL 742887

Footnotes

1 Although there is no separate count for an FCA retaliation claim in her live pleading, Voorhees claims in the prayer for relief that she is entitled to "damages that are as yet indeterminable, for violations of the False Claims Act, 31 U.S.C. [§] 3730(h)." Dkt. 20 at 10. Section 3730(h) is the whistleblower provision of FCA, which prohibits harassment, retaliation, or threatening of employees who assist in or bring *qui tam* actions. Out of an abundance of caution, Kelsey-Seybold requests that, to the extent Voorhees intended to assert a FCA retaliation claim, such a claim should be dismissed under Rule 12(b)(6) for failure to allege the essential elements. In her response to the motion to dismiss, Voorhees did not address Kelsey-Seybold's arguments regarding retaliatory discharge. As a result, she has abandoned the claim and it may be properly dismissed. *See* *Vela v. City of Houston*, 276 F.3d 659, 678–79 (5th Cir. 2001).